EFSA BIOHAZ Panel (EFSA Panel on Biologicial Hazards), 2013. Scientific Opinion on the public health hazards to be covered by inspection of meat (solipeds)

EFSA Publication

Link to article, DOI:
10.2903/j.efsa.2013.3263

Publication date:
2013

Document Version
Publisher's PDF, also known as Version of record

European Food Safety Authority

EFSA Journal 2013;11(6):3263

SCIENTIFIC OPINION

Scientific Opinion on the public health hazards to be covered by inspection of meat (solipeds)[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2,3]

With the contribution of the EFSA Panels on Contaminants in the Food Chain (CONTAM) and Animal Health and Welfare (AHAW)

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

A risk ranking process identified *Trichinella* spp. as the most relevant biological hazard in the context of meat inspection of domestic solipeds. Without a full and reliable soliped traceability system, it is considered that either testing all slaughtered solipeds for *Trichinella* spp., or inactivation meat treatments (heat or irradiation) should be used to maintain the current level of safety. With regard to general aspects of current meat inspection practices, the use of manual techniques during current *post-mortem* soliped meat inspection may increase microbial cross-contamination, and is considered to have a detrimental effect on the microbiological status of soliped carcass meat. Therefore, the use of visual-only inspection is suggested for "non-suspect" solipeds. For chemical hazards, phenylbutazone and cadmium were ranked as being of high potential concern. Monitoring programmes for chemical hazards should be more flexible and based on the risk of occurrence, taking into account Food Chain Information (FCI), covering the specific on-farm environmental conditions and individual animal treatments, and the ranking of chemical substances, which should be regularly updated and include new hazards. Sampling, testing and intervention protocols for chemical hazards should be better integrated and should focus particularly on cadmium, phenylbutazone and priority "essential substances" approved for

[1] On request from the European Commission, Question Nos EFSA-Q-2011-00367, EFSA-Q-2011-00962 and EFSA-Q-2011-01038, adopted on 6 June 2013.

[2] Panel members: Olivier Andreoletti, Dorte Lau Baggesen, Declan Bolton, Patrick Butaye, Paul Cook, Robert Davies, Pablo S. Fernández Escámez, John Griffin, Tine Hald, Arie Havelaar, Kostas Koutsoumanis, Roland Lindqvist, James McLauchlin, Truls Nesbakken, Miguel Prieto, Antonia Ricci, Giuseppe Ru, Moez Sanaa, Marion Simmons, John Sofos and John Threlfall. Correspondence: biohaz@efsa.europa.eu

[3] Acknowledgement: The BIOHAZ Panel wishes to thank the members of the BIOHAZ Working Group on the public health hazards to be covered by inspection of meat (solipeds): Declan Bolton, Sava Buncic, Henrik Elvang Jensen, Edoardo Pozio and Antonia Ricci, the CONTAM Panel: Diane Benford, Sandra Ceccatelli, Bruce Cottrill, Michael DiNovi, Eugenia Dogliotti, Lutz Edler, Peter Farmer, Peter Fürst, Laurentius (Ron) Hoogenboom, Helle Katrine Knutsen, Anne-Katrine Lundebye Haldorsen, Manfred Metzler, Carlo Stefano Nebbia, Michael O'Keeffe, Ivonne Rietjens, Dieter Schrenk, Vittorio Silano, Hendrik van Loveren, Christiane Vleminckx and Pieter Wester, the members of the CONTAM Working Group on meat inspection and contaminants: Johanna Fink-Gremmels, Reinhard Fries, Peter Fürst, Steven McOrist, Carlo Nebbia and Michael O'Keeffe, the AHAW Panel: Edith Authie, Charlotte Berg, Anette Bøtner, Howard Browman, Ilaria Capua, Aline De Koeijer, Klaus Depner, Mariano Domingo, Sandra Edwards, Christine Fourichon, Frank Koenen, Simon More, Mohan Raj, Liisa Sihvonen, Hans Spoolder, Jan Arend Stegeman, Hans-Hermann Thulke, Ivar Vågsholm, Antonio Velarde, Preben Willeberg and Stéphan Zientara, the members of the AHAW Working Group on meat inspection: Donald Broom, Marcus Doherr, Mariano Domingo, Frank Koenen, Hanspeter Meier, Simon More, Pascal Oltenacu, Mohan Raj, Moez Sanaa, Mo Salman, Martin Wierup and Preben Willeberg, for the preparatory work on this scientific opinion, and ECDC (European Centre for Disease Prevention and Control) staff: Eva Warns-Petit and Vicente Lopez Chavarrias, and EFSA staff: Pietro Stella, Ernesto Liébana, Elena Mazzolini (BIOHAZ), Silvia Inés Nicolau-Solano, Valeriu Curtui, Gina Cioacata (CONTAM), Karen Mackay, Milen Georgiev, Ana Afonso (AHAW) for the support provided to this scientific opinion.

Suggested citation: EFSA BIOHAZ Panel (EFSA Panel on Biologicial Hazards), 2013. Scientific Opinion on the public health hazards to be covered by inspection of meat (solipeds). EFSA Journal 2013;11(6):3263, 161 pp. doi:10.2903/j.efsa.2013.3263

Available online: www.efsa.europa.eu/efsajournal

treatment of equine animals. Implementation and enforcement of a more robust and reliable identification system throughout the European Union is needed to improve traceability of domestic solipeds. Meat inspection is recognised as a valuable tool for surveillance and monitoring of animal health and welfare conditions. If visual only *post-mortem* inspection is implemented for routine slaughter, a reduction in the detection of strangles and mild cases of rhodococcosis would occur. However, this was considered unlikely to affect the overall surveillance of both diseases. Improvement of FCI and traceability were considered as not having a negative effect on animal health and welfare surveillance.

KEY WORDS

meat inspection, soliped, horse, slaughterhouse, surveillance, contaminants, residues

SUMMARY

Following a request from the European Commission, the EFSA Panel on Biological Hazards (BIOHAZ) was asked to deliver a scientific opinion on the public health hazards to be covered by inspection of meat for several animal species, with the contribution of the Panel on Contaminants in the Food Chain (CONTAM) and the Panel on Animal Health and Welfare (AHAW). Briefly, the main risks for public health that should be addressed by meat inspection were identified and ranked, the strengths and weaknesses of the current meat inspection system were evaluated, and recommendations were made regarding inspection methods fit for purpose to meet the overall objectives of meat inspection for hazards currently not covered by the meat inspection system, and recommendations for adaptations to inspection methods and/or frequencies of inspections that provide an equivalent level of protection were made. In addition, the implications for animal health and animal welfare of any changes proposed to current inspection methods were assessed. This opinion covers the inspection of meat from domestic solipeds.

Decision trees were developed and used for priority ranking of the biological and chemical hazards at meat inspection. All biological hazards for which any evidence of soliped meat-borne transmission exists and which are currently present in the European Union (EU) soliped population were considered. Hazards introduced and/or for which the risk for public health requires growth during steps following carcass chilling were excluded from the ranking. The priority ranking was based on assessment of: (i) the magnitude of the impact on human health based on incidence; (ii) the severity of the disease in humans; and (iii) the strength of evidence that meat from solipeds is an important risk factor. Risk ranking of chemical hazards into categories of potential concern was based on the outcomes of the national residue control plans (NRCPs), as defined in Council Directive 96/23/EC for the period 2005-2010, and of other testing programmes, as well as on substance-specific parameters such as the toxicological profile and the likelihood of the occurrence of chemical residues and contaminants in solipeds.

Based on the ranking for biological hazards, *Bacillus anthracis*, pathogenic verocytotoxin-producing *Escherichia coli* (VTEC), *Salmonella* spp. (including extended-spectrum β-lactamase (ESBL)/AmpC gene-carrying *Salmonella* spp.), *Yersinia enterocolitica* and *Trichinella* spp. were all classified as hazards of low priority with regard to soliped meat inspection. However, for *Trichinella* spp., the low priority level was judged to be derived from the current hazard-specific control measures applied at the EU level, and in particular from the systematic testing of soliped carcasses for the parasite, and therefore meat inspection-related aspects of *Trichinella* spp. are discussed further in the opinion. *Toxoplasma gondii* was not classified in terms of priority with regard to soliped meat inspection because of insufficient data.

For chemical hazards, phenylbutazone and cadmium were ranked as being of high potential concern owing to their toxicological properties and because of the occurrence of non-compliant results in NRCP testing; all other substances were ranked as of medium or lower concern. It should be noted that the ranking into specific risk categories of chemical hazards is based on current knowledge and available data, and therefore ranking should be updated regularly, taking account of new information and data and including 'new hazards'.

The assessment of the strengths and weaknesses of the current meat inspection regarding biological hazards focused on the public health risks that may occur through the handling, preparation and/or consumption of soliped meat. Strengths identified were that, in principle, utilising food chain information (FCI) to better focus *ante-mortem* and/or *post-mortem* meat inspection is beneficial. *Ante-mortem* inspection enables the detection of clinically observable zoonotic diseases, animal identification enabling traceability and visual evaluation of the cleanliness of animals. *Post-mortem* inspection enables the detection of macroscopic lesions associated with some biological hazards causing zoonotic diseases, e.g. glanders and strangles (non-meat-borne), as well as detection of *Trichinella* spp. by laboratory examination.

With regard to chemical hazards, it was noted that current procedures for sampling and testing are, in general, well established and coordinated including follow-up actions subsequent to the identification of non-compliant samples. The system of issuing of a single lifetime identification document (passport), where it is entirely implemented and properly enforced, should allow for information on traceability, changes of ownership and follow-up procedures.

A number of weaknesses were also identified. The current soliped traceability system does not include compulsory recording in databases of all movements of solipeds from birth to slaughter. Currently FCI is used only to a limited extent and does not include sufficient data to classify solipeds in relation to the meat safety risk associated with the handling, preparation and consumption of soliped meat. There is no evidence to suggest that *ante-mortem* visual assessment of the cleanliness of solipeds is routinely applied in practice. Manual handling of meat, including the use of palpation/incision techniques during *post-mortem* inspection, mediates cross-contamination, although it does not contribute to the detection of relevant hazards, i.e. *Trichinella* spp. Microbial agents associated with common pathological conditions detected at *post-mortem* inspection of solipeds (e.g. pneumonia, abscesses) are caused by non-zoonotic and/or zoonotic hazards, and the latter generally pose an occupational rather than a food-borne risk.

For chemical hazards, a major weakness is that the presence of chemical residues and contaminants generally cannot be identified by current *ante-/post-mortem* meat inspection procedures. Moreover, the level of sampling and the substances to be tested for in solipeds is poorly defined across the EU, and this is reflected in the variability of sampling intensity between MSs. In addition, FCI for domestic solipeds over their entire lifetime may be incomplete or difficult to obtain and this may compromise traceability. Moreover, because solipeds are commonly regarded as companion/sport/working animals, some animals may receive treatments that are not permitted for food-producing animals. Animals treated as non-food-producing animals may enter the food chain as a result of the current improper application/enforcement throughout the EU of the identification (passport) and traceability system.

'New' chemical hazards identified are largely persistent organic pollutants that have not been comprehensively covered by the sampling plans of the current meat inspection or which have not been included in such sampling plans. Due to the nature of the husbandry systems applied and the age to which solipeds may be kept they are more likely to have a build-up of persistent environmental contaminants than some other farm animals; therefore sampling and testing plans should be developed for these chemical hazards.

Possible adaptations to the current meat inspection for *Trichinella* spp. were considered. At present, without a full and reliable soliped traceability system, it is considered that either testing all slaughtered solipeds for *Trichinella* spp. according to Commission Regulation (EC) No 2075/2005 or inactivation meat treatments should be used to maintain the current level of safety. Heat- and irradiation-based treatments can be effective for *Trichinella* spp. inactivation in soliped meat, as long as reliable identification and handling of all parts of animals during the conversion of soliped carcasses into meat cuts, as well as throughout the subsequent treatments applied, is efficiently ensured.

With regard to general aspects of the current meat inspection practices, the use of manual techniques (palpation, incision) during current *post-mortem* soliped meat inspection may increase microbial cross-contamination and thus is considered to have a detrimental effect on the microbiological status of soliped carcass meat. Omitting routine palpation/incision and the use of visual-only inspection would be desirable for 'non-suspect' solipeds. In solipeds considered as 'suspect' (based on FCI and/or *ante-mortem* examination and/or visual detection of relevant conditions), where more detailed examination is necessary, palpation and incision and, in cases in which glanders is suspected, splitting of the head should be performed away from the slaughter line.

Implementation and enforcement of a more robust and reliable identification system throughout the EU is needed to improve traceability of domestic solipeds.

In relation to biological hazards, a series of further recommendations are made on harmonised data collection, hazard identification and priority ranking, and on the implementation of a harmonised FCI data collection and analysis.

Regarding chemical hazards, future monitoring programmes should be based on the risk of occurrence of chemical residues and contaminants, taking into account the completeness and quality of the FCI supplied and the ranking of chemical substances into categories of potential concern. Control programmes should be less prescriptive, with sufficient flexibility to adapt to the results of testing and should include 'new hazards'. There is a need for improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants, particularly cadmium, which has at high prevalence above maximum levels (MLs) in soliped samples. It is recommended that testing for phenylbutazone is specifically included in the NRCPs for solipeds and also testing for priority 'essential substances' that are approved for treatment of equine animals. A series of further recommendations, dealing with control measures, testing and analytical techniques, is made in relation to chemical hazards.

The implications for the surveillance of animal health and welfare of the changes proposed to the current meat inspection system were evaluated quantitatively and qualitatively. The proposed changes from the assessment on the biological hazards included omission of palpation and incision in animals subjected to routine slaughter at *post-mortem* inspection, improvement of animal traceability and improvement of the FCI system. The recommendations from the assessment on the chemical hazards included the ranking of chemical substances of potential concern and its updating, the use of FCI to help facilitate risk based sampling strategies and the inclusion of 'new hazards' in control programmes for chemical residues and contaminants.

From the quantitative analysis, significant reduction in the overall effectiveness of the meat inspection procedure in the visual-only scenario was seen for strangles, probably owing to the omission of palpation of upper respiratory tract lymph nodes in the visual only procedure. The probability of detecting milder cases of rhodococcosis was also significantly reduced in the visual only scenario. In mild cases of rhodococcosis, small abscesses can be located deep in the lung parenchyma and palpation is an important way of detecting them.

The consequences of the reduction in the detection of strangles and rhodococcosis following a change from the current inspection system to a visual only one were analysed qualitatively by experts. The expert opinion is that the expected reduction in the detection level of strangles is unlikely to affect overall surveillance of this disease. In the case of rhodococcosis, mild cases of this disease may go undetected under the visual only scenario; however, the impact of this reduction was considered very low and therefore the change to a visual only system is unlikely to affect overall surveillance of this disease.

Improvement of FCI and traceability were considered by the experts as not having a negative effect on animal health and welfare surveillance.

The assessment on animal health and welfare concluded that the recommendations on chemical hazards would not have a negative impact on surveillance of animal diseases and welfare conditions.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 854/2004[4] of the European Parliament and of the Council lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Inspection tasks within this Regulation include:

- Checks and analysis of food chain information
- *Ante-mortem* inspection
- Animal welfare
- *Post-mortem* inspection
- Specified risk material and other by-products
- Laboratory testing

The scope of the inspection includes monitoring of zoonotic infections and the detection or confirmation of certain animal diseases without necessarily having consequences for the placing on the market of meat. The purpose of the inspection is to assess if the meat is fit for human consumption in general and to address a number of specific hazards, in particular the following issues: transmissible spongiform encephalopathies (only ruminants), cysticercosis, trichinosis, glanders (only solipeds), tuberculosis, brucellosis, contaminants (e.g. heavy metals), residues of veterinary drugs and unauthorised substances or products.

During their meeting on 6 November 2008, Chief Veterinary Officers (CVO) of the Member States agreed on conclusions on modernisation of sanitary inspection in slaughterhouses based on the recommendations issued during a seminar organised by the French Presidency from 7 to 11 July 2008. The CVO conclusions have been considered in the Commission Report on the experience gained from the application of the Hygiene Regulations, adopted on 28 July 2009. Council Conclusions on the Commission report were adopted on 20 November 2009 inviting the Commission to prepare concrete proposals allowing the effective implementation of modernised sanitary inspection in slaughterhouses while making full use of the principle of the 'risk-based approach'.

In accordance with Article 20 of Regulation (EC) No 854/2004, the Commission shall consult EFSA on certain matters falling within the scope of the Regulation whenever necessary.

EFSA and the Commission's former Scientific Committee on Veterinary Measures relating to Public Health have issued in the past a number of opinions on meat inspection considering specific hazards or production systems separately. In order to guarantee a more risk-based approach, an assessment of the risk caused by specific hazards is needed, taking into account the evolving epidemiological situation in Member States. In addition, methodologies may need to be reviewed taking into account risks of possible cross-contamination, trends in slaughter techniques and possible new inspection methods.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The scope of this mandate is to evaluate meat inspection in order to assess the fitness of the meat for human consumption and to monitor food-borne zoonotic infections (public health) without jeopardising the detection of certain animal diseases nor the verification of compliance with rules on animal welfare at slaughter. If and when the current methodology for this purpose would be considered not to be the most satisfactory to monitor major hazards for public health, additional

[4] Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Official Journal of the EU L 139, 30.4.2004, p. 206–320.

methods should be recommended as explained in detail under points 2 and 4 of the terms of reference. The objectives of the current legal provisions aimed at carrying out meat inspection on a risk-based analysis should be maintained.

In order to ensure a risk-based approach, EFSA is requested to provide scientific opinions on meat inspection in slaughterhouses and, if considered appropriate, at any other stages of the production chain, taking into account implications for animal health and animal welfare in its risk analysis. In addition, relevant international guidance should be considered, such as the Codex Code of Hygienic Practice for Meat (CAC/RCP 58–2005), and Chapter 6.2 on Control of biological hazards of animal health and public health importance through *ante*- and *post-mortem* meat inspection, as well as Chapter 7.5 on slaughter of animals of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE).

The following species or groups of species should be considered, taking into account the following order of priority identified in consultation with the Member States: domestic swine, poultry, bovine animals over six weeks old, bovine animals under six weeks old, domestic sheep and goats, farmed game and domestic solipeds.

In particular, EFSA, in consultation with the European Centre for Disease Prevention and Control (ECDC), is requested within the scope described above to:

1. Identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e.g. breeding compared to fattening animals).

2. Assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at *ante-mortem* or *post-mortem* inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.

3. If new hazards currently not covered by the meat inspection system (e.g. *Salmonella, Campylobacter*) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.

4. Recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria (see Annex 2). When appropriate, food chain information should be taken into account.

APPROACH TAKEN TO ANSWER THE TERMS OF REFERENCE

1. Scope

The scope of the mandate is to evaluate meat inspection in a public health context; animal health and welfare issues are also covered with respect to the possible implications of adaptations/alterations to current inspection methods or the introduction of novel inspection methods proposed by this mandate.

Issues other than those of public health significance but that still compromise fitness of the meat for human consumption (Regulation (EC) No 854/2004, Annex I, section II, chapter V) are outside the scope of the mandate. Transmissible spongiform encephalopathies (not relevant though for solipeds) are also outside the scope of the mandate.

The impact of changes to meat inspection procedures on the occupational health of abattoir workers, inspectors, etc. is outside the scope of the mandate. In addition, biological hazards representing primarily occupational health risks, the controls related to any biological hazards at any meat chain stage beyond the abattoir and the implications for environmental protection are not dealt with in this document.

2. Approach

In line with Article 20 of Regulation (EC) No 854/2004[5] the European Commission has recently submitted a mandate to EFSA (M-2010-0232) to cover different aspects of meat inspection. The mandate comprises two requests: one for scientific opinions and one for technical assistance.

EFSA is requested to issue scientific opinions related to inspection of meat in different species. In addition, technical assistance has been requested on harmonised epidemiological criteria for specific hazards for public health that can be used by risk managers to consider adaptation of meat inspection methodology.

Meat inspection is defined by Regulation (EC) No 854/2004. The species or groups of species to be considered are: domestic swine, poultry, bovine animals over six weeks old, bovine animals under six weeks old, domestic sheep and goats, farmed game and domestic solipeds.

Taking into account the complexity of the subject and the fact that consideration has to be given to zoonotic hazards, animal health and welfare issues and to chemical hazards (e.g. residues of veterinary drugs and chemical contaminants), the involvement of several EFSA Units was necessary. More specifically, the mandate was allocated to the Panel on Biological Hazards (BIOHAZ Panel) which prepared this opinion with the support of the Panels on Animal Health and Welfare (AHAW Panel) and Contaminants in the Food Chain (CONTAM Panel).

This scientific opinion therefore concerns the assessment of meat inspection in domestic solipeds, and it includes the answer to the terms of reference proposed by the European Commission. Owing to the complexity of the mandate, the presentation of the outcome does not follow the usual layout. For ease of reading, main outputs from the three working groups (BIOHAZ, CONTAM and AHAW) are presented at the beginning of the document. The scientific justifications of these outputs are found in the various appendices as endorsed by their respective Panels, namely biological hazards (Appendix A), chemical hazards (Appendix B), and the potential impact that the proposed changes envisaged by these two could have on animal health and welfare (Appendix C).

[5] OJ L 226, 25.6.2004, p.83-127.

CONCLUSIONS AND RECOMMENDATIONS ANSWERING THE TERMS OF REFERENCE

CONCLUSIONS

TOR 1. ***Identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e.g. breeding compared to fattening animals).***

Conclusions on biological hazards

- Identification and priority ranking of the main risks for public health that should be addressed by soliped meat inspection was hampered by the lack of animal and carcass surveillance and epidemiological data.

- According to the decision tree developed, and based on the limited data available, the identified soliped meat-borne biological hazards were categorised as follows:

  - *Trichinella* spp. was assessed as a hazard of low priority with regard to soliped meat inspection. However, this low priority level was judged to be derived from the current hazard-specific control measures applied at the EU level, and in particular from the systematic testing of soliped carcasses for the parasite implemented at the slaughterhouse level in the EU according to meat inspection legislative requirements. Therefore, in agreement with the ranking methodology developed, meat inspection-related aspects of *Trichinella* spp. are discussed further in the opinion.

  - *Toxoplasma gondii* was not classified in terms of priority with regard to soliped meat inspection because of insufficient data.

  - *Bacillus anthracis*, pathogenic verocytotoxin-producing *Escherichia coli* (VTEC), *Salmonella* spp. (including extended-spectrum β-lactamase (ESBL)/AmpC gene-carrying *Salmonella* spp.) and *Yersinia enterocolitica* were classified as hazards of low priority with regard to soliped meat inspection. This low priority level was judged not to be derived from the current hazard-specific control measures applied at the EU level.

Conclusions on chemical hazards

- A multi-step approach was used for the identification and ranking of chemical hazards. Evaluation of the 2005–2010 national residue control plans (NRCPs) outcome for solipeds indicated that 2.28 % of the total number of results was non-compliant for one or more substances listed in Council Directive 96/23/EC. Available data, however, do not allow for a reliable assessment of consumer exposure.

- Ranking of chemical residues and contaminants in domestic solipeds based on pre-defined criteria, relating to bioaccumulation, toxicological profile and likelihood of occurrence and taking into account the findings from the NRCPs for the period 2005–2010 was as follows:

  - Phenylbutazone was ranked as being of high potential concern owing to its toxicological properties and proven human toxicity and because of the occurrence of non-compliant results in NRCP testing.

  - The environmental contaminant, cadmium, was ranked as being of high potential concern because of its toxicological properties and because of the occurrence of non-compliant results in NRCP testing.

- Residues originating from other substances listed in Council Directive 96/23/EC were ranked as being of low or negligible potential concern owing to the toxicological profile of these substances at residue levels in edible tissues or to the very low or non-occurrence of non-compliant results in the NRCPs 2005–2010. Potentially higher exposure of consumers to these substances from horse meat takes place only incidentally, as a result of non-compliance with known and regulated procedures. However, baseline monitoring for the occurrence of substances currently ranked as of low or negligible potential concern in solipeds is desirable.

TOR 2. ***Assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at ante-mortem or post-mortem inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.***

Conclusions on biological hazards

- Strengths:
  - In principle, utilising food chain information (FCI) to better focus *ante-mortem* and/or *post-mortem* meat inspection is beneficial.
  - *Ante-mortem* inspection enables the detection of clinically observable zoonotic diseases, animal identification enabling traceability and visual evaluation of the cleanliness of animals.
  - *Post-mortem* inspection enables the detection of macroscopic lesions associated with some biological hazards causing zoonotic diseases, e.g. glanders and strangles (non-meat-borne), as well as detection of *Trichinella* spp. by laboratory examination.
  - *Ante-mortem* and *post-mortem* inspection detect visible faecal contamination of the skin and dressed carcasses, which is relevant for potential cross-contamination of the meat.
- Weaknesses:
  - The current soliped traceability system does not include compulsory recording in databases of all movements of solipeds from birth to slaughter.
  - Currently FCI is used only to a limited extent and does not include sufficient data to classify solipeds in relation to the meat safety risk associated with the handling, preparation and consumption of soliped meat.
  - There is no evidence to suggest that *ante-mortem* visual assessment of the cleanliness of solipeds is routinely applied in practice.
  - Manual handling of meat, including the use of palpation/incision techniques during *post-mortem* inspection aimed at the detection of some non-zoonotic and/or zoonotic but non-meat-borne hazards, mediates cross-contamination. It does not contribute to the detection of relevant hazards, i.e. *Trichinella* spp. Hence, these two opposing effects of palpation/incision have to be considered carefully to ensure an overall benefit for public health. To a lesser extent, such cross-contamination concerns may also be related to manual sampling for *Trichinella* spp. testing.

- Microbial agents associated with common pathological conditions detected at *post-mortem* inspection of solipeds (e.g. pneumonia, abscesses) are caused by non-zoonotic and/or zoonotic hazards, and the latter generally pose an occupational rather than a food-borne risk.

- Judgement of the fitness of meat for human consumption in current *post-mortem* inspection does not differentiate food safety aspects (related to the spread of soliped meat-borne hazards through the food chain) from meat quality aspects, prevention of animal diseases and occupational hazards.

Conclusions on chemical hazards

- Strengths:

  - The current procedures for sampling and testing are a mature system, which is in general well established and coordinated, including follow-up actions subsequent to the identification of non-compliant samples.

  - The system of issuing of single lifetime identification documents (passports), where it is entirely implemented and properly enforced, should allow for information on traceability, changes of ownership, and follow-up procedures.

- Weaknesses:

  - Presence of chemical hazards generally cannot be detected by current *ante-/post-mortem* meat inspection procedures.

  - Solipeds are commonly regarded as companion/sport/working animals and thus some animals may receive treatments that are not permitted for food-producing animals.

  - The single lifetime identification document (passport) system currently is not properly applied/enforced throughout the EU. This may result in animals treated as non-food-producing animals entering the food chain.

  - Solipeds come to slaughter at variable ages (up to 30 years old) and may have been reared on a number of different holdings and in low numbers. The animals often come from mixed holdings rearing both food-producing and non-food-producing solipeds, and sometimes following lengthy transport prior to slaughter. All these factors may result in the FCI for these animals over their entire lifetime being incomplete or difficult to obtain and this may compromise traceability.

  - At present, the level of sampling and the substances to be tested for is poorly defined across the EU. This is reflected in the variability of sampling intensity among MSs.

Conclusions on animal health and welfare

- As shown by COMISURV, with a change from the current to a visual only inspection system, a significant reduction (non-overlapping 90 % probability intervals) in the overall effectiveness of the meat inspection procedure was seen only for strangles. Nevertheless, the resulting probability of detection was still very high (≥ 0.9).

- *Post-mortem* inspection plays a minor role in the diagnosis and surveillance of strangles and therefore a change to a visual only system is unlikely to affect overall surveillance of this disease.

- The prevalence of animal welfare conditions in solipeds arriving in slaughterhouses in Europe is not well documented.

- The proposed change to visual only meat inspection is not expected to affect the detection of animal welfare conditions.

- Improvements in traceability, as recommended from the assessment on biological hazards, are expected to have a positive impact on surveillance of diseases and welfare conditions in solipeds.

- Food chain information is a potentially effective tool to perform more targeted *ante-mortem* and *post-mortem* inspection tasks in the slaughterhouse that may increase the effectiveness of those tasks in detecting conditions of significance for animal health and animal welfare.

- The existing ineffective flow of information from primary production to the slaughterhouses and vice versa reduces the ability to detect animal diseases and animal welfare conditions at the slaughterhouse, and as a result it limits possible improvements on animal health and welfare standards as owners and responsible persons will not be aware of the slaughterhouse findings.

- None of the conclusions and recommendations on chemical hazards were considered to have an impact on animal health and welfare surveillance and monitoring.

TOR 3. ***If new hazards currently not covered by the meat inspection system (e.g. Salmonella, Campylobacter) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.***

Conclusions on biological hazards

- No specific amendments of the current meat inspection methodology are discussed or recommended as any hazard not currently covered by meat inspection were classified as low priority in the answer to TOR 1.

Conclusions on chemical hazards

- 'New hazards' are defined as compounds that have been identified as anthropogenic chemicals in food-producing animals and derived products and in humans and for which occurrence data in solipeds are scarce and which may not be systematically covered by the NRCPs. Examples are polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans (together often termed 'dioxins'), dioxin-like PCBs (DL-PCBs), non dioxin-like PCBs (NDL-PCBs), brominated flame retardants, such as polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), and perfluorinated compounds, such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA).

- Owing to the nature of the husbandry systems and the age to which solipeds may be kept, they are more likely to have a build-up of persistent environmental contaminants than some other farm animals.

TOR 4. ***Recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria (see Annex 2). When appropriate, food chain information should be taken into account.***

Conclusions on biological hazards

- In principle, separation of solipeds during the pre-slaughter phase (i.e. on farm) into lower or higher risk categories with respect to *Trichinella* spp. could be based on certain criteria including the breeding system (high vs. non-high containment system), and/or geographical origin (origin from countries/regions where *Trichinella* spp. is present or not in the domestic and sylvatic cycles).

- Indoor farming of solipeds is not an applicable option, and reliable traceability is a prerequisite for the geographical risk categorisation of animals with respect to *Trichinella* spp., therefore such an option could be applicable on the basis of origin only in cases in which the traceability of movements of solipeds is fully guaranteed.

- In a risk-based system, carcasses from low-risk solipeds could be passed without having to be either *Trichinella* spp. tested or subject to *Trichinella* spp. inactivation treatments. In contrast, meat from higher risk solipeds could undergo one of two options: either to be examined for *Trichinella* spp. or to be treated by a reliable and validated larvae-inactivating treatment.

- At present, without a full and reliable soliped traceability system, it is considered that either testing all slaughtered solipeds for *Trichinella* spp. according to Commission Regulation (EC) No 2075/2005 or inactivation meat treatments should be used to maintain the current level of safety.

- Heat- and irradiation-based treatments can be effective for *Trichinella* spp. inactivation in soliped meat, as long as reliable identification and handling of all parts of animals during the conversion of soliped carcasses into meat cuts, as well as throughout the subsequent treatments applied, is efficiently ensured.

- The use of manual techniques (palpation, incision) during current *post-mortem* soliped meat inspection may increase microbial cross-contamination.

- Taking into account the results of the priority ranking performed, the spread of microbial hazards on soliped carcass/meat as a result of cross-contamination caused by routine palpation/incisions cannot be regarded as posing a high degree of concern for public health. However, any cross-contamination, including that mediated by palpation/incision techniques, is considered to have a detrimental effect on the microbiological status of soliped carcass meat.

- The majority of gross lesions that are currently detected in slaughtered solipeds in the EU by palpation/incision do not pose a serious threat to public health, hence omitting routine palpation/incision and the use of visual-only inspection would be desirable for 'non-suspect' solipeds. In solipeds considered as 'suspect' (based on FCI and/or *ante-mortem* examination and/or visual detection of relevant conditions), where more detailed examination is necessary, palpation and incision and, in cases in which glanders is suspected, splitting of the head should be performed away from the slaughter line.

Conclusions on chemical hazards

- For solipeds, the FCI should provide information on the specific environmental conditions on the farms where the animals are reared as well as the individual animal history, including treatments with substances other than those listed in Table 1 of the Annex to Regulation (EU) No 37/2010 and those 'essential substances' listed in the Annex to Commission Regulation (EU) No 122/2013.

- It is a matter of concern that a relatively large number of samples were non-compliant for the NSAID phenylbutazone and for the environmental contaminant cadmium.

RECOMMENDATIONS

Recommendations on biological hazards

- Traceability (identification and movements) systems for solipeds intended for slaughter should be improved in order to improve the FCI in relation to their origin and movements throughout their life.

- Because the hazard identification and ranking relates to the EU as a whole, refinements reflecting differences among regions or production systems are recommended if/where hazard monitoring indicates.

- Furthermore, as new hazards might emerge and/or hazards that at present are not a priority might become more relevant over time or in some regions, both hazard identification and the ranking are to be revisited regularly to reflect this dynamic epidemiological situation.

- Insufficient/lack of data and related assessment uncertainties were issues in the priority ranking exercise in this opinion. This was particularly relevant for *T. gondii*, for which it was impossible to reach a definitive conclusion about the priority ranking. Hence, it is recommended that data on the occurrence of viable *T. gondii* tissue cysts are collected.

- In order to improve future ranking exercises it is imperative that harmonised data are collected on:

  - the incidence and severity of human diseases caused by relevant hazards;

  - source attribution;

  - the identification and ranking of emerging hazards that could be transmitted through handling, preparation and consumption of soliped meat.

- The development and implementation of a harmonised FCI data collection and analysis system for the main hazards in solipeds at both the farm and the abattoir level are recommended.

Recommendations on chemical hazards

- A more robust and reliable identification system is needed to improve the traceability of domestic solipeds. Individual lifetime identification of domestic solipeds and the 'passport' system (Commission Decision 2000/68/EC, Commission Regulation (EC) No 504/2008) should be strengthened, implemented and enforced throughout the EU.

- Future monitoring programmes should be based on the risk of occurrence of chemical residues and contaminants, taking into account the completeness and quality of the FCI supplied and

the ranking of chemical compounds into categories of potential concern, which ranking needs to be regularly updated. Control programmes should be less prescriptive, with sufficient flexibility to adapt to results of testing and should include 'new hazards'.

- There is a need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants, particularly for cadmium which occurs at high prevalence above maximum levels (MLs) in soliped samples.

- It is recommended to specifically include in the NRCPs for solipeds testing for phenylbutazone and, also, testing for priority 'essential substances' listed in Commission Regulation (EU) No 122/2013 to check compliance with withdrawal periods.

- The development of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into feed control and chemical residues and contaminants testing in the NRCPs. Moreover, a minimum number of samples, proportional to the production (slaughtered animals) for each MS, should be specified in NRCPs in order to ensure an equal level of control across the EU.

Recommendations on animal health and welfare

- Studies are needed to ascertain the prevalence of animal welfare conditions in solipeds arriving in slaughterhouses in Europe.

- An integrated system should be developed whereby food chain information for public health and for animal health and welfare can be used in parallel, more effectively.

- For effective surveillance of diseases and welfare conditions one should be able to trace back animal movements up to slaughter.

- Owners or responsible persons should be provided with background information on the conditions of key concern that may affect their animals and why it is important to provide this information to the slaughterhouse through the use of food chain information.

APPENDICES

Appendix A. Assessment on biological hazards

SUMMARY

This appendix of the opinion deals with the biological public health hazards to be covered by meat inspection in domestic solipeds. All soliped species are considered together (i.e. horses, donkeys and their cross-breeds). All hazards for which any evidence of soliped meat-borne transmission exists and which are currently present in the European Union (EU) soliped population were considered. A decision tree was developed and used for priority ranking of these hazards. Hazards introduced and/or for which the risk for public health requires growth during steps following carcass chilling were excluded from the ranking. The priority ranking was based on assessment of: (i) the magnitude of the impact on human health based on incidence; (ii) the severity of the disease in humans; and (iii) the strength of evidence that meat from solipeds is an important risk factor. Based on this ranking, *Bacillus anthracis*, pathogenic verocytotoxin-producing *Escherichia coli* (VTEC), *Salmonella* spp. (including extended-spectrum β-lactamase (ESBL)/AmpC gene-carrying *Salmonella* spp.), *Yersinia enterocolitica* and *Trichinella* spp. were all classified as hazards of low priority with regard to soliped meat inspection. However, for *Trichinella* spp., the low priority level was judged to be derived from the current hazard-specific control measures applied at the EU level, and in particular from the systematic testing of soliped carcasses for the parasite, and therefore meat inspection-related aspects of *Trichinella* spp. are discussed further in the opinion. *Toxoplasma gondii* was not classified in terms of priority with regard to soliped meat inspection because of insufficient data.

The assessment of the strengths and weaknesses of the current meat inspection focused on the public health risks that may occur through the handling, preparation and/or consumption of soliped meat. Considerations of the handling and preparation were restricted to handling of soliped meat by consumers or professional food handlers immediately prior to consumption.

Strengths identified were that, in principle, utilising food chain information (FCI) to better focus *ante-mortem* and/or *post-mortem* meat inspection is beneficial. *Ante-mortem* inspection enables the detection of clinically observable zoonotic diseases, animal identification enabling traceability and visual evaluation of the cleanliness of animals. *Post-mortem* inspection enables the detection of macroscopic lesions associated with some biological hazards causing zoonotic diseases, e.g. glanders and strangles (non-meat-borne), as well as detection of *Trichinella* spp. by laboratory examination. *Ante-mortem* and *post-mortem* inspection detect visible faecal contamination of the skin and dressed carcasses, which is relevant for potential cross-contamination of the meat.

A number of weaknesses were also identified. The current soliped traceability system does not include compulsory recording in databases of all movements of solipeds from birth to slaughter. Currently FCI is used only to a limited extent and does not include sufficient data to classify solipeds in relation to the meat safety risk associated with the handling, preparation and consumption of soliped meat. There is no evidence to suggest that *ante-mortem* visual assessment of the cleanliness of solipeds is routinely applied in practice. Manual handling of meat, including the use of palpation/incision techniques during *post-mortem* inspection, mediates cross-contamination, although it does not contribute to the detection of relevant hazards, i.e. *Trichinella* spp. Microbial agents associated with common pathological conditions detected at *post-mortem* inspection of solipeds (e.g. pneumonia, abscesses) are caused by non-zoonotic and/or zoonotic hazards, and the latter generally pose an occupational rather than a food-borne risk.

Possible adaptations to the current meat inspection for *Trichinella* spp. were considered. In principle, separation of solipeds during the pre-slaughter phase (i.e. on farm) into lower or higher risk categories with respect to *Trichinella* spp. could be based on certain criteria including the breeding system (high vs non-high containment system) and/or geographical origin (origin from countries/regions where *Trichinella* spp. is present or not in the domestic and sylvatic cycles). In a risk-based system, carcasses

from low-risk solipeds could be passed without having to be either *Trichinella* spp. tested or subject to *Trichinella* spp. inactivation treatments. However, indoor farming of solipeds is not an applicable option, and reliable traceability is a prerequisite for the geographical risk categorisation of animals with respect to *Trichinella* spp. At present, without a full and reliable soliped traceability system, it is considered that either testing all slaughtered solipeds for *Trichinella* spp. according to Commission Regulation (EC) No 2075/2005 or inactivation meat treatments should be used to maintain the current level of safety. Heat- and irradiation-based treatments can be effective for *Trichinella* spp. inactivation in soliped meat, as long as reliable identification and handling of all parts of animals during the conversion of soliped carcasses into meat cuts, as well as throughout the subsequent treatments applied, is efficiently ensured.

With regard to general aspects of the current meat inspection practices, the use of manual techniques (palpation, incision) during current *post-mortem* soliped meat inspection may increase microbial cross-contamination and thus is considered to have a detrimental effect on the microbiological status of soliped carcass meat. Omitting routine palpation/incision and the use of visual-only inspection would be desirable for 'non-suspect' solipeds. In solipeds considered as 'suspect' (based on FCI and/or *ante-mortem* examination and/or visual detection of relevant conditions), where more detailed examination is necessary, palpation and incision and, in cases in which glanders is suspected, splitting of the head should be performed away from the slaughter line.

It is recommended that the traceability systems for solipeds intended for slaughter should be improved. A series of further recommendations are made on harmonised data collection, hazard identification and priority ranking, and on the implementation of a harmonised FCI data collection and analysis.

TABLE OF CONTENTS

ASSESSMENT

1. Introduction

1.1. Definition of meat inspection and remit of the opinion

Assessing current meat inspection systems for solipeds with the aim of introducing improvements requires a common understanding of the term 'meat inspection'. However, as discussed previously, it seems that there is no precise, universally agreed definition of *meat inspection* (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011, 2012). The term *meat inspection* is not described specifically in current European Union (EU) legislation (Regulation (EC) No 854/2004) or in the Codex Alimentarius's Code of Hygienic Practice for Meat (CAC/RCP 58-2005); rather, there are references to elements of the inspection process for meat such as *ante-* and *post-mortem* inspection and Food Chain Information (FCI). Consequently, the current understanding of the term *meat inspection* is probably based more on its practical application, and somewhat intuitive, than on a specific, formal definition.

The Panel on Biological Hazards (BIOHAZ) defined the main scope of the biological hazards assessment as identifying and ranking the most relevant biological public health risks associated with meat from domestic solipeds, assessing the strengths and weaknesses of the current meat inspection system and proposing alternative approaches for addressing current meat safety risks. Biological hazards representing only occupational health risks, the controls related to any biological hazards at any meat chain stage beyond abattoir, and the implications for environmental protection are not dealt with in this document.

For the purpose of this document 'domestic solipeds' are intended as the animals belonging to the species *Equus caballus* (horses), *Equus asinus* (donkeys) and their cross-breeds (i.e. mules and hinnies). As the EU Regulations do not include different inspection requirements for the different domestic soliped species, they are considered together.

In order to support the work of the BIOHAZ Panel and of its working group in drafting the BIOHAZ scientific opinion on the public health hazards to be covered by inspection of meat (solipeds), the EFSA BIOHAZ Unit organised a technical hearing with EU stakeholder organisations linked to the remit of the mandate. The aim was to collect relevant information in relation to production, slaughter, consumption and inspection of meat from domestic solipeds (EFSA, 2012).

Chemical hazards and associated solipeds meat safety risks are considered in a separate part of this opinion. Although the public health aim of improving the biological/chemical safety of meat is prioritised, the implications for animal health and animal welfare of any changes are also considered in a separate part of this opinion. Furthermore, issues related to epidemiological indicators and associated sampling/testing methodologies for hazards dealt with in this opinion are addressed by the EFSA Unit on Biological Monitoring (BIOMO) in a separate report (EFSA, 2013b). For information on those other hazards or aspects, the reader is referred to those documents.

1.2. Production and consumption of domestic solipeds in the EU

Compared with production of meat from other species, production of meat from domestic solipeds is limited in the EU and is generally concentrated in a limited number of countries and regions. Based on the last available data provided by Member States (MSs) within the framework of Directive 96/23/EC, approximately 260 000 horses were slaughtered in the EU in 2010, primarily in Italy, Poland, Spain and Romania (EFSA, 2013a) (Table 1). Messina (2007) reported that in 2006 in Italy the vast majority of solipeds slaughtered were horses, with donkeys representing only 0.77 % (1 280 head) and mules/hinnies only 0.04 % (62 head) of the total. In other EU countries the soliped meat industry is less developed. For example, Leadon et al. (2012) report that in Ireland deliberate breeding of horses

for the production of meat, as well as horse meat consumption in general, are not traditional practices. However, solipeds may be employed in sport or work or as companion animals and be slaughtered at the end of their careers, unless the owner explicitly declares in the passport that the animal should not be intended for slaughter for human consumption. As reported in the EFSA technical hearing of stakeholders (EFSA, 2012), holdings rearing solipeds for meat production are often small/medium-sized holdings, sometimes farming more species on the same premises. The age of the animals slaughtered is variable (from 1 to 30 years).

Table 1: Horses slaughtered in EU MSs in 2010 (EFSA, 2013a).

Country	Production	Country	Production
Austria	947	Latvia	400
Belgium	12 000	Lithuania	2 250
Bulgaria	214	Luxembourg	0
Cyprus	6 800	Malta	173
Czech Republic	336	Netherlands	2 083
Denmark	1 872	Poland	45 152
Estonia	0	Portugal	907
Finland	1 179	Romania	27 520
France	15 468	Slovakia	0
Germany	8 937	Slovenia	1 578
Greece	0	Spain	29 638
Hungary	394	Sweden	3 940
Ireland	7 449	United Kingdom	5 062
Italy	84 063	**Total EU-27**	**258 362**

Consumption is variable between countries and regions. Soliped meat is usually consumed as cooked fresh cuts, and in some areas it is also consumed as raw minced meat. A small proportion of the meat reaches consumers as meat preparations. Offal from solipeds is usually not consumed (EFSA, 2012). Data in relation to consumption of meat from domestic solipeds in the EU are scarce but confirm that its consumption is unevenly distributed among different EU countries. Of the consumer surveys that have been completed in EU countries, results show that the percentage of people interviewed who declared consumption of soliped meat varied from 0 % to 3 %, with a variable average daily consumption (Table 2). Some additional data on consumption were provided quite regularly by MSs to EUROSTAT up to 2007. For that year, the average consumption of meat from domestic solipeds was reported to vary from no consumption to 1 kg per head, depending on the country (EFSA, 2013b).

Table 2: Soliped meat consumption in some EU MSs, as result of consumer surveys. The number of reporting days varies depending on the survey. Results from different surveys undertaken in the same country and age category are reported in some cases. Source: EFSA Consumption Database.

Country	Age class	Surveyed subjects	Number of soliped meat consumers (%)	Average consumption (g/day)	
				Consumers only	All surveyed subjects
Belgium	Toddlers	36	1 (2.8 %)	70.0	1.9
	Other children	625	8 (1.3 %)	22.4	0.3
	Adolescents	584	6 (1.0 %)	72.4	0.7
	Adults	1 304	16 (1.2 %)	85.7	1.1
	Elderly	518	11 (2.1 %)	47.2	1.0
	Very elderly	712	8 (1.1 %)	71.2	0.8
Bulgaria	Toddlers	428	0		
	Other children	433	0		
	Infants	860	0		
Cyprus	Adolescents	303	0		
Czech Republic	Other children	389	0		
	Adolescents	298	0		
	Adults	1 666	0		
Denmark	Other children	490	0		
	Adolescents	479	0		
	Adults	2 822	0		
	Elderly	309	0		
	Very elderly	20	0		
Finland	Toddlers	497	0		
	Other children (i)	933	0		
	Other children (ii)	250	0		
	Adults	1 575	0		
	Elderly	463	0		
France	Other children	482	9 (1.9 %)	14.9	0.3
	Adolescents	973	21 (2.2 %)	23.1	0.5
	Adults	2 276	52 (2.3 %)	23.7	0.6
	Elderly	264	8 (3.0 %)	19.2	0.6
	Very elderly	84	0		
Germany	Toddlers (i)	92	0		
	Toddlers (ii)	85	0		
	Toddlers (iii)	84	0		
	Other children (i)	211	0		
	Other children (ii)	226	0		
	Other children (iii)	223	0		
	Adolescents	1 011	0		
	Adults	10 419	2 (0.02 %)	118.3	0.02
	Elderly	2 006	0		
	Very elderly	490	0		
Greece	Other children	839	0		
Hungary	Adults	1 074	0		
	Elderly	206	0		
	Very elderly	80	0		
Ireland	Adults	958	0		
Italy	Toddlers	36	0		
	Infants	16	0		
	Other children	193	1 (0.5 %)	50.7	0.3

Country	Age class	Surveyed subjects	Number of soliped meat consumers (%)	Average consumption (g/day)	
				Consumers only	All surveyed subjects
	Adolescents	247	8 (3.2 %)	39.5	1.3
	Adults	2 313	57 (2.5 %)	47.4	1.2
	Elderly	290	8 (2.8 %)	47.0	1.3
	Very elderly	228	5 (2.2 %)	33.14	0.73
Latvia	Other children	189	0		
	Adolescents	470	0		
	Adults	1 306	0		
Netherlands	Toddlers	322	0		
	Other children	957	2 (0.2 %)	7.15	0.01
	Adults	750	2 (0.3 %)	16.78	0.04
Spain	Toddlers	17	0		
	Other children (i)	156	1 (0.6 %)	100.00	0.64
	Other children (ii)	399	2 (0.5 %)	85.50	0.43
	Adolescents (i)	86	0		
	Adolescents (ii)	209	2 (1.0 %)	67.50	0.65
	Adolescents (iii)	651	1 (0.2 %)	66.00	0.10
	Adults (i)	410	0		
	Adults (ii)	981	0		
Sweden	Other children	1 473	15 (1.0 %)	5.07	0.05
	Adolescents	1 018	9 (0.9 %)	11.17	0.10
	Adults	1 210	8 (0.7 %)	9.29	0.06
United Kingdom	Adults	1 724	0		

2. Hazard identification and risk ranking

2.1. Hazard identification

2.1.1. Methodology

The first step in the hazard identification was to identify microbiological hazards that occur in solipeds in Europe and that may be transmissible to humans through the handling, preparation and/or consumption of soliped meat. In the context of this opinion, when referring to *handling and preparation* this should be interpreted as handling of soliped meat that occurs immediately prior to consumption, when these activities are carried out by consumers or professional food handlers such as those in catering establishments. The hazards were identified based on evidence found in the peer-reviewed literature, textbooks, official data (e.g. EU summary reports on zoonoses), previous assessments and EFSA opinions, and, when all other evidence was lacking, based on the expert opinion of the BIOHAZ Panel and the BIOHAZ Working Group on "meat inspection of solipeds".

A list of all zoonotic hazards occurring in solipeds was established ('longlist'). Thereafter the relevance of each hazard in the context of meat inspection was evaluated based on the two following criteria:

1. Is there any evidence that the hazard can be transmitted to humans through the handling, preparation and/or consumption of soliped meat?

2. Is there evidence that the hazard is present in the EU soliped population?

The hazards in the 'longlist' that met these two criteria were included in the 'shortlist' of hazards to be considered further.

2.1.2. Results

Following the methodology explained in Section 2.1.1, the zoonotic hazards occurring in solipeds included in the preliminary longlist of hazards are presented in Table 3.

Table 3: Longlist of zoonotic hazards and main transmission routes to humans.

Hazard		**Main transmission routes to humans**
Bacteria	*Actinobacillus equuli*	Direct contact and animal bites
	Actinobacillus lignieresii	Direct contact and animal bites
	Aeromonas hydrophila	Primarily water borne, also food-borne
	Bacillus anthracis	Aerosols and contact infection, and may be soliped meat-borne
	Bacillus cereus	Food-borne. The emetic form requires growth and toxin production in food and is usually associated with starchy foods such as rice. The diarrhoeic form is usually associated with diary and meat products. May be soliped meat-borne
	Brucella abortus	Contact infection, can be food-borne (primarily milk)
	Burkholderia mallei	Aerosols and contact infection, food-borne route (milk) was suggested, but not meat-borne
	Burkholderia pseudomallei	Aerosols and contact infection, rarely food-borne (primarily milk) but not meat-borne
	Thermophilic *Campylobacter* spp.	Food-borne, primarily poultry but also pork, beef and lamb. No evidence for soliped meat contamination
	Clostridium botulinum *Clostridium difficile*	Food-borne and may be soliped meat-borne Primarily human-to-human contact

Hazard		Main transmission routes to humans
	Clostridium perfringens	Food-borne and may be soliped meat-borne
	Coxiella burnetii	Aerosols, may be food-borne (primarily milk)
	Dermatophilus congolensis	Primarily direct contact
	Pathogenic VTEC	Food-borne, including soliped meat-borne
	ESBL/AmpC gene-carrying *Escherichia coli*	Food-borne, but no evidence of soliped meat-borne
	Leptospira spp.	Direct contact and aerosols
	Listeria monocytogenes	Food-borne and may be soliped meat-borne
	Mycobacterium bovis, *tuberculosis* and *avium*	Primarily aerosols but may be acquired by direct contact and possibly food-borne but not soliped meat-borne
	Pasteurella multocida	Aerosols and contact infection
	Rhodococcus equi	Direct contact and aerosols
	Salmonella spp.	Food-borne, including soliped meat-borne
	ESBL/AmpC gene-carrying *Salmonella* spp.	Food-borne, including soliped meat-borne
	Staphylococcus aureus	Food-borne and may be soliped meat-borne
	Meticillin-resistant *Staphylococcus aureus* (MRSA)	Primarily a hospital acquired infection, also direct contact, has been isolated from raw meat but food-borne transmission not demonstrated
	Streptococcus equi (including *S. equi zooepidemicus*)	Primarily acquired by direct contact and possibly food-borne but not soliped meat-borne
	Yersinia enterocolitica	Food-borne, including soliped meat-borne
	Yersinia pseudotuberculosis	Water and food-borne, including meat, but no evidence of soliped meat-borne
Fungi	Dermatophytes (e.g. *Trichophyton* spp. and *Microsporum* spp.)	Direct contact
Parasites	*Cryptosporidium* spp.	Water and food-borne, but no evidence of soliped meat-borne
	Echinococcus granulosus	Ingestion due to cross-contamination from dog faeces
	Giardia duodenalis	Water and food-borne, but no evidence of soliped meat-borne
	Toxoplasma gondii	Water and food-borne, including meat, limited evidence of soliped meat-borne
	Trichinella spp.	Meat-borne, including soliped meat-borne
Viruses	*Bunyaviridae*, *Orthobunyavirus* (California encephalitis virus)	Vector borne
	Flaviviridae, *Flavivirus* (West Nile virus, Japanese encephalitis virus, St. Louis encephalitis virus)	Vector borne and in a limited number of cases direct contact
	Hepeviridae, *Hepevirus* (hepatitis E virus)	Water and food-borne, but no evidence of soliped meat-borne
	Monegavirales, *Bornaviridae*, *Bornavirus* (Borna disease virus)	Direct & indirect contact
	Monegavirales, *Paramyxoviridae*, *Henipavirus* (Nipah virus, Hendra virus)	Direct contact
	Monegavirales, *Rhabdoviridae*, *Lyssavirus* (rabies virus)	Bites
	Monegavirales, *Rhabdoviridae*, *Vesiculovirus* (vesicular stomatitis viruses)	Vector borne and direct contact
	Togaviridae, *Alphavirus* (eastern equine encephalitis virus, western equine encephalitis virus, Venezuelan equine encephalitis virus, Barmah forest virus, Ross River virus)	Vector borne

Each of those hazards was assessed with respect to the two criteria defined in Section 2.1.1 (i.e. soliped meat-borne transmission criterion and the presence in the EU population criterion) (see Table 4). A brief description of the information considered to give the answers to those questions is given in Section 2.2.3 (hazards selected for ranking) and in Annex A (hazards not selected for ranking).

For a number of hazards that can be transmitted through meat, evidence of their occurrence in soliped meat or of transmission through soliped meat is absent or limited. For example, no evidence of transmission through soliped meat has been found in relation to *A. hydrophila*, *Campylobacter* spp., *S. equi*, *Y. pseudotuberculosis*, *Cryptosporidium* spp. and *G. duodenalis*, and therefore those hazards were not shortlisted. Limited evidence (epidemiological studies) suggests soliped meat-borne transmission for *T. gondii*.

The following zoonotic hazards were considered to be soliped meat-borne and evidence could be found of food-borne transmission through the handling, preparation and/or consumption of soliped meat: *B. anthracis*, *B. cereus*, *C. botulinum*, C. *perfringens*, pathogenic VTEC, *L. monocytogenes*, *Salmonella* spp. (including ESBL/AmpC gene-carrying *Salmonella* spp.), *S. aureus*, *Y. enterocolitica*, *T. gondii* and *Trichinella* spp. (Table 5). Each of these hazards was considered in the priority ranking.

Table 4: Results of the assessment against the two criteria (i.e. evidence of soliped meat-borne and presence in the EU soliped population), leading to the shortlist of biological hazards. The question related to the second criterion is answered only when a positive reply is provided to the question related to the first criterion.

Biological hazard	Any evidence of soliped meat-borne transmission?	Currently present in the EU soliped population?	Included in the shortlist for priority ranking?	Examples of recent supporting evidence for inclusion
Bacteria				
Actinobacillus equuli	No	–	No	
Actinobacillus lignieresii	No	–	No	
Aeromonas hydrophila	No	–	No	
Bacillus anthracis	**Yes**	**Yes**	**Yes**	Purcell et al. (2007)[a]
Bacillus cereus	**Yes**	**Yes**	**Yes**	Ubiquitous hazard[b]
Brucella abortus	No	–	No	
Burkholderia mallei	No	–	No	
Burkholderia pseudomallei	No	–	No	
Thermophilic *Campylobacter* spp.	No	–	No	
Clostridium botulinum	**Yes**	**Yes**	**Yes**	Ubiquitous hazard[b]
Clostridium difficile	No	–	No	
Clostridium perfringens	**Yes**	**Yes**	**Yes**	Ubiquitous hazard[b]
Coxiella burnetii	No	–	No	
Dermatophilus congolensis	No	–	No	
Pathogenic VTEC	**Yes**	**Yes**	**Yes**	Pichner et al. (2001); Gill (2005)
ESBL/AmpC gene-carrying *Escherichia coli*	No	–	–	
Leptospira spp.	No	–	No	
Listeria monocytogenes	**Yes**	**Yes**	**Yes**	Ubiquitous hazard[b]
Mycobacterium bovis, *tuberculosis* and *avium*	No	–	No	
Pasteurella multocida	No	–	No	
Rhodococcus equi	No	–	No	
***Salmonella* spp.**	**Yes**	**Yes**	**Yes**	Catsaras (1966); Espie et al. (2005)
ESBL/AmpC gene-carrying *Salmonella* spp.	**Yes**	**Yes**	**Yes**	Espie et al. (2005)
Staphylococcus aureus	**Yes**	**Yes**	**Yes**	Ubiquitous hazard[b]
Meticillin-resistant *Staphylococcus aureus*	No	–	No	
Streptococcus equi (including *S. equi zooepidemicus*)	No	–	No	
Yersinia enterocolitica	**Yes**	**Yes**	**Yes**	Gill (2005)
Yersinia pseudotuberculosis	No	–	No	
Fungi				
Dermatophytes (e.g. *Trichophyton* spp. and *Microsporum* spp.)	No	–	No	
Parasites				
Cryptosporidium spp.	No	–	No	
Echinococcus granulosus	No	–	No	
Giardia duodenalis	No	–	No	
Toxoplasma gondii	**Yes**	**Yes**	**Yes**	Elbez-Rubenstein et al. (2009); Pomares et

Biological hazard	Any evidence of soliped meat-borne transmission?	Currently present in the EU soliped population?	Included in the shortlist for priority ranking?	Examples of recent supporting evidence for inclusion
				al. (2011)
***Trichinella* spp.**	**Yes**	**Yes**	**Yes**	Gill (2005); Liciardi et al. (2009)
Viruses				
Bunyaviridae, Orthobunyavirus (California encephalitis virus)	No	–	No	
Flaviviridae, Flavivirus (West Nile virus, Japanese encephalitis virus, St. Louis encephalitis virus)	No	–	No	
Hepeviridae, Hepevirus (hepatitis E virus)	No	–	No	
Monegavirales, Bornaviridae, Bornavirus (Borna disease virus)	No	–	No	
Monegavirales, Paramyxoviridae, Henipavirus (Nipah virus, Hendra virus)	No	–	No	
Monegavirales, Rhabdoviridae, Lyssavirus (rabies virus)	No	–	No	
Monegavirales, Rhabdoviridae, Vesiculovirus (vesicular stomatitis virus)	No	–	No	
Togaviridae, Alphavirus (eastern equine encephalitis virus, western equine encephalitis virus, Venezuelan equine encephalitis virus, Barmah forest virus, Ross River virus)	No	–	No	

a: See also: www.promedmail.org/direct.php?id=20010601.1083; www.promedmail.org/direct.php?id=20080830.2720; www.promedmail.org/direct.php?id=20081123.3699; www.promedmail.org/direct.php?id=20130601.1748961

b: The hazard is ubiquitous and can potentially be transmitted through consumption, preparation and handling of meat, but it is generally not possible to identify the original source of the contamination.

Table 5: Shortlist of soliped meat-borne hazards.

Bacteria	*Bacillus anthracis*
	Bacillus cereus
	Clostridium botulinum
	Clostridium perfringens
	Pathogenic VTEC
	Listeria monocytogenes
	Salmonella spp.
	ESBL/AmpC gene-carrying *Salmonella* spp.
	Staphylococcus aureus
	Yersinia enterocolitica
Parasites	*Toxoplasma gondii*
	Trichinella spp.

2.2. Priority ranking

2.2.1. Methodology

The hazards in Table 5 were ranked according to the priority to be given to them when considering whether they should be addressed by meat inspection. A decision tree, developed by the BIOHAZ Panel was used as a tool for this ranking exercise (see Figure 1).

This decision tree was adapted from that presented in the EFSA opinion on meat inspection of poultry (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2012). However, there are key differences as follows:

- The term 'priority' replaced the term 'risk', previously employed. In order to carry out informed risk ranking at EU level, sufficient and robust data should be available both on the occurrence of the relevant hazards and on the attributable fraction of the different hazard meat–species combinations to human disease. In the former EFSA opinions on meat inspection of swine and poultry, there were sufficient data at EU level available for the relevant hazards (i.e. EU-wide baseline surveys, harmonised monitoring, etc.) that provided the scientific basis for the ranking (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011, 2012). However, similar data were not available for meat from domestic solipeds, and the term 'priority' was considered to be more appropriate than 'risk' when categorising the relevance of the different hazards.

- Carcass pathogen prevalence and source attribution are not considered as separate questions, or ranking steps, but these two questions are addressed together in a single step, as follows: 'Is there evidence for meat from solipeds as an important risk factor?". This modification was considered appropriate as there were insufficient data at EU level for qualifying carcass prevalence and source attribution for the given hazards. Furthermore, soliped meat consumption is very small in the EU relative to meat for other animal species such as pigs or poultry. Attribution at the population level, as applied in the previous opinions, may not provide a sufficiently detailed perspective on the relative risk of different hazards in soliped meat.

The modified decision tree therefore includes the following steps:

Step 1: Identifies and excludes those hazards that are introduced and/or for which the risk for public health requires growth during steps following carcass chilling. The reasons for excluding such hazards from further assessment were that:

- The scope and target of meat inspection are focused on hazards present on the final soliped carcass at the end of slaughter when the carcasses are chilled.

- Hazards introduced and/or for which the risk relates to growth during post-chilling processes or steps are better controlled later in the food-production chain through, for instance, various interventions and hazard analysis and critical control point (HACCP)-based control programmes.

Step 2: Assesses the magnitude of the human health impact based on incidence, as measured by the notification rate or reported number of confirmed cases. Human disease data were supplied by The European Surveillance System (TESSy) and covered the years 2008, 2009, 2010 and 2011 (Table 6). They were supplied as combined data for all EU reporting MSs, without specifying particular countries. A human incidence ≥ 10/100 000 of the population was considered to be high.

Step 3: Assesses the severity of the disease in humans, measured by percentage of cases resulting in death (Table 6). Hazards were judged to have a high severity if the fatality rate exceeds 1 per 1 000 in more than one year. As before, these thresholds are based on previous EFSA opinions (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011, 2012).

Step 4: Evaluates the strength of evidence that meat from solipeds is an important risk factor, based on the following criteria considered in order of priority:

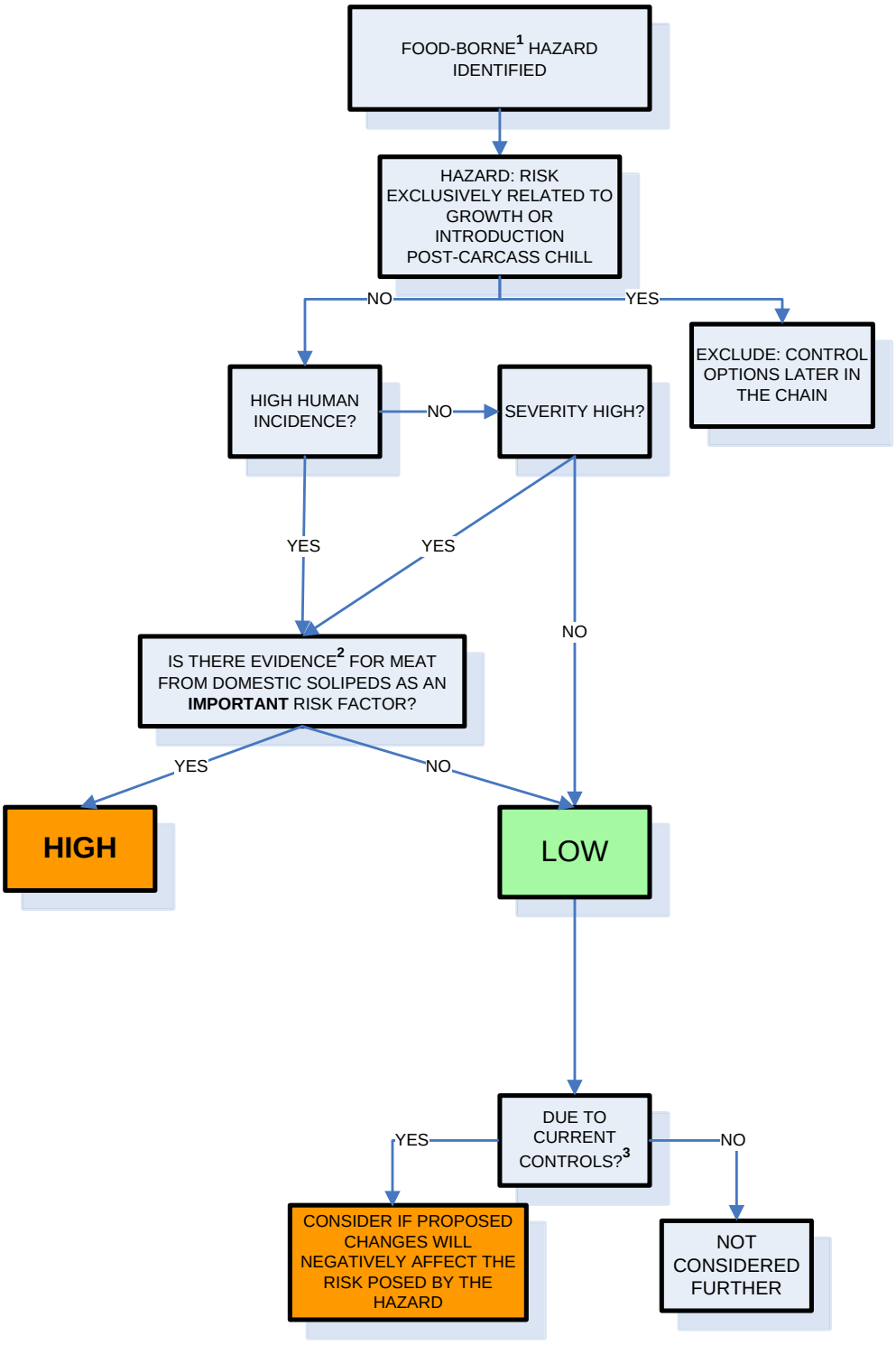
- epidemiological link, based on a significant association of consumption of soliped meat as a risk factor for human cases or on outbreak data;
- carcass-prevalence/farm-level prevalence data;
- comparative considerations for meat from related species and data from outside the EU;
- expert opinion that soliped meat consumption is a risk factor.

Data or studies from within the EU/EEA (European Economic Area) were preferred, but in their absence other relevant sources of data were considered. The final outcome of this process was assigning each hazard to one of two priority categories ('high' or 'low') defined as follows:

- The priority was characterised as 'high' when a hazard was identified as associated with a high incidence and/or severity of illness in humans, and when strong evidence existed for soliped meat being an important risk factor for human disease. Considering the limitations of the data available for the priority ranking, this priority category could be regarded as combining both the medium- and the high-risk categories of the risk ranking carried out in the poultry meat inspection opinion.
- The priority was characterised as 'low' when a hazard was identified as associated with a low incidence and a low severity of human disease, or when, despite the hazard causing a high incidence and/or severity in humans, there is not evidence for meat from domestic solipeds being an important risk factor for human disease.

The priority was characterised as 'undetermined' if the data available for the assessment of a given biological hazard were insufficient to draw conclusions on the ranking.

All hazards placed in the low-priority category were further evaluated to determine if this was low because of currently applied controls (i.e. any hazard-specific control measure implemented at farm and/or slaughter level before chilling of the carcass, including meat inspection procedures). If this was not the case, the hazard was not considered further. However, if this was the case, then the hazard was further considered and the effect of any recommendations regarding the removal of specific control measures or meat inspection activities on these hazards was carefully evaluated.



[1] In the context of this opinion, food-borne is defined as transmission of the hazard through the handling, preparation and/or consumption of soliped meat. *Handling and preparation* are interpreted as handling of soliped meat by consumers or professional food handlers during preparation immediately prior to consumption.
[2] Evidence based on (i) epidemiological link, (ii) carcass prevalence/farm level prevalence, (iii) comparative considerations with meat from other species and (iv) expert opinion. Please see further details in the text.
[3] Current controls: any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures.

Figure 1: Decision tree providing a priority ranking of shortlisted soliped meat-borne hazards.

2.2.2. Data employed for the priority ranking

2.2.2.1. Human incidence and severity data in the EU

Human incidence and severity data were provided by the European Centre for Disease Prevention and Control (ECDC) (Table 6). The data supplied by TESSy cover the years 2008, 2009, 2010 and 2011. The data supplied are officially reported to ECDC (TESSy) by the 27 EU MSs, according to Commission Decision 2012/506/EU. However, some countries do not report on certain diseases, as specified in Table 6. The data were supplied as aggregates from all reporting MSs. Data show notification rates of confirmed human disease cases per 100 000 persons, and severity of illness in humans. Cases include all reported confirmed occurrences of the disease, regardless of the origin of the infection. In fact, establishing the food related origin of infection is often not possible and seldom reported. The data on severity include as a proxy the proportion of confirmed human cases that died out of the cases for which complete information was available. Indeed, this information is usually only present in a small proportion of cases. Finally, it has to be kept in mind that the surveillance systems are set up differently in the various EU MSs, with different case definitions, national or restricted coverage, voluntary or compulsory reporting, different focus, target group etc., in addition to the fact that only a small fraction of disease is sampled and the casual organism typed and reported to the respective national health institutes. Because of all the above caveats, the incidence and severity figures quoted here are only approximate and must be considered with caution, along with the rest of data and information contained in this opinion.

Information on ESBL in *E. coli* in the TESSy database is extremely scarce. Limited case-based data on susceptibility to cefotaxime are available in the TESSy database for *E. coli* and *Salmonella* spp. causing disease in humans. These can be used to approximate third-generation cephalosporin resistance.

Disability-adjusted life year (DALY) estimates for the Netherlands were available as an alternative indicator for disease severity, as presented in Table 7. The DALY metric encompasses the impact of mortality as well as morbidity, and is based on estimates of the true incidence of acute disease as well as sequelae. The disease burden per case therefore represents a more comprehensive measure of disease severity than reported hospitalisations and deaths. It is noted, however, that DALY data are currently only available for the Netherlands and cannot be directly extrapolated to the whole EU situation. However, many parameters that contribute to the disease burden per case are not country specific, supporting the use of the Dutch results in an EU setting. Other parameters may depend on the healthcare system or other factors that are specific to individual countries. ECDC has initiated the 'Burden of Communicable Diseases in Europe (BCoDE)' project, which aims to estimate the burden of communicable diseases, including food- and water-borne diseases, applying the DALY metric.[6]

2.2.2.2. Carcass and animal occurrence data in the EU

Table 8 reports available data concerning the occurrence of certain soliped meat-borne hazards in solipeds and meat thereof. Data were reported to EFSA by the EU MSs and some non-MSs under Directive 2003/99/EC (Zoonoses Directive). Data described as originating from suspect or selective sampling and from clinical investigations are excluded for the reason that they do not, in most cases, represent the actual epidemiological situation. Food samples described as collected for HACCP and own-check purposes were excluded because the sampling scheme may be biased. Samples included are described as originating from control and eradication plans and monitoring and surveillance; consequently they are supposed to represent the occurrence of the zoonotic agent in the reporting country over the years, based on objective sampling. However, monitoring and surveillance schemes for most zoonotic agents, especially in the early years of reporting, are not fully harmonised between MSs. Furthermore, in the reporting country data may not necessarily be derived from sampling plans that are statistically designed and may not accurately represent the national situation regarding zoonoses.

[6] See: www.ecdc.europa.eu/en/healthtopics/burden_of_communicable_diseases/project/Pages/project.aspx

No data were available for hazards other than those indicated in the table.

2.2.2.3. Data from other sources

Additional data used to inform the priority ranking are reported and discussed when addressing the individual soliped meat-borne hazards in the following sections.

Table 6: Overall human incidence and severity data reported by EU MSs as described in Decision 2119/98/EC on communicable diseases for selected soliped hazards (independently of the source of infection). Source: TESSy data extraction carried out on 31 January 2013. Data may vary from those presented in former related EFSA opinions on meat inspection of swine and poultry, owing to updates of TESSy data provided by MSs retrospectively.

Selected hazard	Incidence in humans (number of reported confirmed cases per 100 000 EU population[a] [number of confirmed cases])				Severity in humans (percentage of reported deaths[b] [number of confirmed cases with information])			
	2008	2009	2010	2011	2008	2009	2010	2011
Bacillus anthracis	< 0.01 [2]	< 0.01 [14]	0.01 [32]	< 0.01 [6]	100.00 [1]	54.55 [11]	37.93 [29]	25.00 [4]
VTEC (all serogroups)[c]	0.86 [3 156]	0.97 [3 583]	1.00 [3 656]	2.56 [9 478]	0.15 [1 363]	0.35 [1 701]	0.38 [2 108]	0.75 [7 504]
VTEC (O157)[c]	0.35 [1 683]	0.39 [1 888]	0.31 [1 510]	0.45 [2 195]	0.00 [241]	0.94 [318]	0.56 [536]	0.36 [1 110]
Salmonella spp.[d]	29.46 [132 800]	23.81 [108 977]	21.51 [99 590]	20.37 [94 264]	0.09 [72 837]	0.08 [54 273]	0.13 [46 996]	0.12 [46 808]
ESBL/AmpC gene-carrying *Salmonella* spp.	NA	NA	NA	NA	NA	NA	NA	NA
Yersinia enterocolitica[e]	0.16 [7 484]	0.15 [6 856]	0.13 [6 162]	0.14 [6 724]	0.04 [5 314]	0.02 [4 756]	0.00 [4646]	0.02 [4 792]
Toxoplasma gondii (congenital, i.e. in infants <1 year)[f]	0.04 [83]	0.10 [306]	0.07 [279]	0.01 [29]	50.00 [2]	9.62 [260]	5.15 [233]	NA
Trichinella spp.[g]	0. 14 [670]	0.15 [750]	0.05 [223]	0.06 [268]	0.00 [36]	0.00 [295]	0.00 [126]	0.37 [205]

a: EU population data based on individual MS population sizes reported in Eurostat (data extracted in September 2012). When the given hazard was not reported by a MS to TESSy, the population size reported by that MS was also taken out of the calculation of the overall EU population size.
b: Calculated as the percentage of cases with fatal outcome over all cases of disease with known outcome, for a given hazard.
c: Portugal not reporting. For a more detailed review of VTEC (including serotype O157) incidence and severity in the EU see the EFSA Opinion on VTEC-seropathotype and scientific criteria regarding pathogenicity assessment (EFSA, 2013).
d: *Salmonella* Typhi and Paratyphi serotypes not included; Netherlands not reporting.
e: Greece, Netherlands, Portugal not reporting.
f: Belgium, Denmark, Greece, Italy, Netherlands, Portugal, Sweden not reporting; Spain reporting through sentinel system and thus not taken into account; France has not yet reported in 2011 (at the time of extraction of the data).
g: Denmark not reporting.
NA: not available.

Table 7: DALY estimates per 1 000 cases of illness for 2009 in the Netherlands (Havelaar et al., 2012) for selected hazards.

Hazard	DALY estimates per 1 000 cases of illness
Bacillus anthracis	NA
Shiga toxin-producing *Escherichia coli* O157	143
ESBL/AmpC gene-carrying *Salmonella* spp.	NA
Salmonella spp.	49
Yersinia enterocolitica	[40–50][a]
Toxoplasma gondii	3 170–6 360 (acquired/congenital)
Trichinella spp.	NA

a: Assumed to be comparable to *Salmonella* spp.

Table 8: Occurrence of selected soliped meat-borne hazards in solipeds and meat thereof in EU MSs and Norway (2007–2011).

Hazard	Animal occurrence data					Carcass/meat occurrence data				
	Unit	Tested	Positive	Occurrence	MSs	Unit	Tested	Positive	Occurrence	MSs
Pathogenic VTEC	Animal	1 110	9	0.81 %	7	Single	12	0	0 %	2
	Herd	18	0	0 %	2					
Salmonella spp.	Animal	5 351	136	2.54 %	18[a]	Single	328	2	0.61 %	6
	Herd	1 450	72	4.97 %	6[a]	Batch	816	0	0 %	5
Yersinia enterocolitica	Animal	11 216	2	0.02 %	4	Single	5	0	0 %	1
	Batch	44	0	0 %	2					
Toxoplasma gondii	Animal	626	1	0.16 %	7					
Trichinella spp.						Single	775 532	3	0.00 %	28[a]
						Batch	23 354	0	0 %	3

a: Including Norway.

2.2.3. Results

Listeria monocytogenes and toxins of *Bacillus cereus*, *Clostridium botulinum, Clostridium perfringens* and *Staphylococcus aureus* were excluded during the first step of the decision tree, as they were all considered to fall within the category of risk related to growth or introduction post-chill, for different reasons:

- Illness caused by *L. monocytogenes* is usually associated with ready-to-eat products (including soliped meat products), where contaminating organisms have been reduced or eliminated during processing and then re-introduced post processing, e.g. during packaging, and is followed by growth during prolonged storage at refrigeration temperatures.

- *B. cereus*, *C. botulinum*, *C. perfringens* and their spores, and *S. aureus* are considered ubiquitous bacteria, and can be found in a variety of foods. Their vegetative forms need temperatures above those used for refrigeration to grow in raw meat to concentration levels of public health relevance and thus the risk of disease seems not to be correlated with occurrence in raw meat but rather to improper storage that allows the production of toxin.

The above hazards were not considered further.

The following hazards were therefore selected for further ranking: *B. anthracis*, pathogenic VTEC, *Salmonella* spp. (including ESBL/AmpC gene-carrying *Salmonella* spp.), *Y. enterocolitica*, *T. gondii* and *Trichinella* spp. The information used to priority rank these hazards according to step 2 to 4 in the decision tree included human incidence and severity data, and epidemiological evidence for meat from domestic solipeds being an important risk factor (epidemiological link, carcass/farm prevalence, comparative consideration for meat from related species and expert opinion). The evidence and data available are summarised in the text dedicated to the specific hazards below and concludes with the results of the priority ranking. A summary of the priority ranking for all hazards is presented in Table 10.

2.2.3.1. *Bacillus anthracis*

- **Human incidence:** low

Human incidence data for years 2008–2011 indicate an incidence of 0.01 cases or less per 100 000 EU population (Table 6), with a total of 54 cases reported in the four years by six Member States.

- **Severity of disease:** high

According to human severity data available for the years 2008–2011 (Table 6), the reported death rate was 25–100 % among confirmed *B. anthracis* cases in the EU for which complete information was available. No data on the burden of disease are available for *B. anthracis*.

- **Evidence for meat from solipeds as an important risk factor:** no

Anthrax is a zoonotic disease caused by the spore-forming bacterium *B. anthracis*. These bacteria form resistant spores that are ubiquitous in soil around the world, and grazing animals may become infected if they ingest sufficient quantities of these spores. Humans are usually infected with this pathogen via aerosols or direct contact with infected animals. Cases of pulmonary anthrax have been linked to factories processing hides and wool, where aerosolised anthrax spores may have been inhaled when ventilation was inadequate. Cases of gastrointestinal anthrax have resulted from the ingestion of raw or undercooked meat[7] and well-cooked beef from infected animals (CDC, 2000). In general, consumption of meat from carcasses of animals showing clinical signs of anthrax, or that have died from the disease, is the most commonly reported route worldwide of food-borne infection resulting in gastrointestinal anthrax. In the EU in 2010 (most recent ECDC data available), 32

[7] See: http://www.cfsph.iastate.edu/Factsheets/pdfs/anthrax.pdf

confirmed cases of anthrax in humans were reported by three MSs (ECDC, 2013): Bulgaria (3), Germany (1) and the UK (28). Although oropharyngeal and gastrointestinal anthrax in humans may result from ingesting infected meat from horses that has not been sufficiently cooked[8] (Purcell et al., 2007), cases are extremely rare and currently are not considered to be significant in the EU. From non-European countries there are reports of non-solipeds being the source of gastrointestinal anthrax in humans arising from the consumption of infected meat (Beatty et al., 2003).

Data on occurrence of anthrax in solipeds and/or their carcasses are not available in the EU summary reports on zoonoses. Anthrax is now rare in livestock in the European Union. The major enzootic areas are Greece, Spain, France and Southern Italy (Fasanella et al., 2005; Fouet et al., 2002). An outbreak of anthrax was reported among cattle, sheep and horses in southern Italy in 2011, with seven fatal cases in horses.[9] Earlier, a severe outbreak of anthrax occurred in Southern Italy in 2004 (Fasanella et al., 2010), involving several species including horses.

- **Low priority owing to current controls:** no

Currently no specific control measures for *B. anthracis* are applied in solipeds, and the generic hygiene practices in place are not considered to be the reason for the current level of risk related to soliped meat.

2.2.3.2. Pathogenic VTEC

- **Human incidence:** low

Verocytotoxin-producing *Escherichia coli* (VTEC, also known as vero-toxigenic *E. coli*, verocytotoxigenic *E. coli*, verotoxin-producing *E. coli* and Shiga toxin-producing *E. coli* (STEC)) are characterised by the ability to produce potent cytotoxins. Pathogenic VTEC usually harbour also additional virulence factors that are important for the development of the disease in humans (EFSA Panel on Biological Hazards (BIOHAZ), 2013). Not all VTEC strains have been associated with human disease and there is no single or combination of marker(s) that defines a 'pathogenic' VTEC. While *stx*2- and *eae*- positive strains are associated with a high risk of more serious illness, other virulence gene combinations and/or serotypes may also be associated with serious disease in humans. For the purposes of this Opinion, pathogenic VTEC are defined as VTEC capable of causing disease in humans.

Human incidence data for the years 2008–2011 indicate an incidence of 0.31–0.45 cases (O157) and 0.86–2.56 cases (all serogroups) per 100 000 EU population (Table 6).

- **Severity of disease:** high

According to human severity data available for the years 2008–2011 (Table 6), there was a 0–0.94 % mortality rate reported among confirmed VTEC (O157) cases in the EU for which complete information was available.

The severity of illness associated with pathogenic VTEC, and in particular the impact of haemolytic–uraemic syndrome as a sequela, is reflected in a burden of 143 DALYs per 1 000 cases, when considering estimates for the Netherlands (Table 7).

- **Evidence for meat from solipeds as an important risk factor:** no

There is no epidemiological data linking human infection with pathogenic VTEC to soliped meat and the incidence of these pathogens in horse meat is low, ranging from 0 % to 2.3 % (Bacci et al., 2002; Collobert et al., 2001; Pichner et al., 2001), but may be considered as indirect evidence of the possible meat-borne transmission to humans (Gill, 2005; Pichner et al., 2001). Official monitoring data, as

[8] See also: www.promedmail.org/direct.php?id=20010601.1083; www.promedmail.org/direct.php?id=20080830.2720; www.promedmail.org/direct.php?id=20081123.3699; www.promedmail.org/direct.php?id=20130601.1748961

[9] See: www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review?page_refer=MapFullEventReport&reportid=11003

reported in the period 2007–2011 by the EU MSs under the Zoonoses Directive, included only 12 samples from soliped carcasses/meat at slaughterhouse level, all with negative results. A total of 1 128 samples were tested from solipeds' faeces and other unspecified matrices, with 9 positive results (0.81 %) among single animal samples, and no positives among herd samples (Table 8). It was therefore concluded that the evidence available suggests that soliped meat is not an important risk factor with regard to pathogenic VTEC infection.

- **Low priority due to current controls:** no

Currently no specific control measures for pathogenic VTEC are applied in solipeds, and the generic hygiene practices in place are not considered to be the reason for the current level of risk related to soliped meat.

2.2.3.3. *Salmonella* spp., including ESBL/AmpC gene-carrying *Salmonella* spp.

- **Human incidence:** high

Human incidence data for the years 2008–2011 indicate an incidence of 20.37–29.46 cases per 100 000 EU population (Table 6).

- **Evidence for meat from solipeds as an important risk factor:** no

Salmonella spp. infection is the second most frequently reported bacterial zoonosis in Europe (EFSA and ECDC, 2013). Although it is well established that horses are carriers of *Salmonella* spp. (Gill, 2005), there are limited data on the incidence and prevalence of *Salmonella* spp. on soliped carcasses and meat products. Early surveillance work reported caecal, faecal, mesenteric lymph node, muscle tissue and carcass contamination rates of 15 %, 27 %, 18 %, 47 % and 27 %, respectively (Anderson and Lee, 1976; Giorgi, 1973; Monteverde et al., 1969; Quevedo et al., 1973). However, these data are arguably out of date. More recent analysis of fresh horse meat failed to detect this pathogen or reported a low (2 %) incidence (Collobert et al., 2001; Dorey and Collobert, 1999; Pichner et al., 2001; Pollastri et al., 1994).

Official monitoring data available for Europe, recorded under the Zoonoses Directive, indicate that between 2007 and 2011, 2.54 % of 5 351 single animal samples, 4.97 % of 1 450 herd samples, 0.61 % of 328 single carcass/meat samples, and 0 % of 816 batch carcass/meat samples were *Salmonella* spp. positive (Table 8). Among positive results from animal samples, 43 % were reported as *S.* Typhimurium and 42 % as *Salmonella* spp. The remaining 15 % of positive samples included *S.* Abortusequi, *S.* Enteritidis, *S.* Dublin, *S.* Reading, *S.* London, *S.* Abortusovis and *S.* Hadar. The two positive carcass/meat samples were reported as *Salmonella* spp. and *S.* 4,12:i:-.

With regards to ESBL/AmpC gene-carrying *Salmonella* spp., data are limited. Concerning human data, EU-wide TESSy-related data are not available. Concerning animal data, reports of ESBLs associated with solipeds include *S.* Newport MDR-AmpC-expressing TEM-1b and ESBL SHV-12, which caused a major outbreak in animals in the George D. Widener Hospital for large animals at the University of Pennsylvania's New Bolton Center, one of the largest equine hospitals in the USA (Rankin et al., 2005). Clearly these horses were not registered as food-producing animals, and therefore were allowed to be treated with cephalosporins. ESBL *Salmonella* spp. had been previously isolated from horses in the USA (Frye and Fedorka-Cray, 2007).

The epidemiological evidence linking human salmonellosis to the handling, preparation and/or consumption of soliped meat is also limited and mostly out of date. In the north of France an outbreak of *S.* Blockly linked to minced horse meat was reported in 1961 and gave origin to more than 80 human cases, and a further *Salmonella* spp. outbreak, also associated with minced horse meat, caused more than 100 human cases in 1964 (Catsaras, 1966). More recently, one MDR-AmpC *S.* Newport outbreak involving 10 confirmed cases in France in 2001 was linked to the consumption of soliped meat (Espie et al., 2005). Based on the above, it was concluded that soliped meat is not an

important risk factor with regard to *Salmonella* spp. infection, particularly when compared to other animal reservoirs.

- **Low priority due to current controls:** no

When drawing the above conclusions, the Panel also took into account the fact, in contrast to other species (e.g. poultry and in many countries also pigs), that in solipeds no control measures specifically against *Salmonella* spp. are applied in MSs. This indicates that the low prevalence in solipeds is not considered to be due to the implementation of control strategies and is truly lower than what it would probably be in other species, if such controls were not applied.

2.2.3.4. *Yersinia enterocolitica*

- **Human incidence:** low

Human incidence data for years 2008–2011 indicate an incidence of 0.13–0.16 cases per 100 000 EU population (Table 6).

- **Severity of disease:** low

According to human severity data available for years 2008–2011 (Table 6), there was a 0–0.04 % mortality reported among confirmed cases of yersiniosis in the EU for which complete information was available.

No data on the burden of disease are available for *Y. enterocolitica*. However, acute yersiniosis is similar to acute salmonellosis and may lead to the same sequelae (reactive arthritis, irritable bowel syndrome). The case–fatality ratio of yersiniosis is similar to that of campylobacteriosis. Hence, the burden per case of yersiniosis is assumed to be in between the burden of campylobacteriosis and salmonellosis. These three bacterial infections cause a relatively low burden of 40–50 DALYs per 1 000 cases (Table 7).

- **Low priority due to current controls:** no

Currently no specific control measures for *Y. enterocolitica* are applied in solipeds, and the generic hygiene practices in place are not considered to be the reason for the current level of risk related to soliped meat.

2.2.3.5. *Toxoplasma gondii*

T. gondii infection is common in animals and humans. The causative agent is an obligate intracellular protozoan parasite, *T. gondii*. Nearly all warm-blooded animals can act as intermediate hosts, and seemingly all animals may be carriers of tissue cysts of this parasite. However, the parasite develops its sexual cycle in all felid species, which act as definitive hosts, the most important of which are domestic and wild cats (Jones and Dubey, 2012).

- **Human incidence:** low

Human incidence data for congenital toxoplasmosis for the years 2008–2011 indicate an incidence of 0.01–0.1 cases per 100 000 EU population (Table 6).

- **Severity of disease:** high

According to human severity data available for the years 2008–2011 (Table 6), a death rate of 5.15–50 % was reported among confirmed cases of toxoplasmosis in the EU for which complete information was available.

Most human infections are asymptomatic or cause mild flu-like symptoms resulting in long-lasting immunity. Lymphadenitis accompanied by fever and headache are the most frequent clinical symptoms of infection in humans. From 11 % to 67 % of pregnant women of Europe are positive for

anti-*T. gondii* immunoglobulin G (Hall et al., 2001). Occasionally the parasite may cause a serious foetal infection resulting in abortion or congenital lesions in the infant's brain, eyes or other organs, particularly if the mother acquires her first infection during the first trimester of pregnancy.

The burden of toxoplasmosis (in particular congenital toxoplasmosis but also acquired toxoplasmosis) is 10- to 100-fold higher than the burden of the bacterial hazards. This is related to the impact of fetal and neonatal deaths, as well as the long-term impact of lesions in the eye (chorioretinitis). DALY estimates for the Netherlands indicate a burden of 3 170–6 360 DALYs per 1 000 cases of toxoplasmosis (Table 7).

- **Evidence for meat from solipeds as an important risk factor:** undetermined

The infection may be acquired by humans through the consumption of undercooked meat containing intermediate cysts or food/water contaminated with oocysts from cat faeces or from handling contaminated soil or cat litter trays. The attribution of specific human cases of infection (i.e. by oocyst or cyst ingestion) remains generally unknown. A clear route of infection is identified in relatively few outbreaks. For example, the oocyst transmission route was documented in strict vegetarians and in water outbreaks. According to three case–control studies carried out in Europe (Baril et al., 1999; Cook et al., 2000; Kapperud et al., 1996), undercooked meat was identified as the main risk factor associated with *T. gondii* infection in pregnant women. Cook et al. (2000) attributed between 30 % to 63 % of infections to consumption of undercooked meat (lamb, beef or game). Consumption of meat from solipeds was not specifically considered among risk factors on its own, but Cook et al. (2000) considered horse meat together with meat from other species. About 30–50 % of the European human population is estimated to be infected (Hall et al., 2001).

In response to natural infection, most farm animals that are seropositive for *T. gondii* have been shown to harbour infectious parasites in their meat, including game, sheep, goats, horses, chickens, pigs (Kijlstra and Jongert, 2009), and, recently, cattle.[10] Kijlstra and Jongert (2008, 2009) analysed the available information in relation to the role of meat from different animal species in the transmission of *T. gondii* to humans. They concluded that animals with outdoor access can become infected via oral uptake of *T. gondii* oocysts and that the parasite will remain present in their tissues for life. Therefore, animals such as sheep, goats, horses, game and in general animals raised outdoors are at a higher risk of infection and act as a transmission route to humans. These authors summarised seroprevalences in these animals in European countries, together with information on the isolation of *T. gondii* from meat.

According to the scientific and grey literature, there are no confirmed cases of clinical toxoplasmosis in solipeds anywhere in the world (Dubey and Jones, 2008).

Monitoring data, as reported in the period 2007–2011 by the EU MSs in the framework of the Zoonoses Directive, included a total of 626 soliped animal samples tested in 7 MSs (excluding samples derived purely from clinical investigations), with 1 positive result (0.16 %). About 90 sero-surveys to detect anti-*T. gondii* antibodies in horses have been published worldwide. The prevalence of antibodies ranged from 0 % to 90 %, but since 10 diagnostic methods with different specificity and sensitivity have been used in 28 countries (Tassi, 2007), the epidemiological significance of the serological positivity remains questionable. A recent study performed in the south of Spain reported a seroprevalence of 10.8 % in horses, 15.0 % in mules and 25.6 % in donkeys (Garcia-Bocanegra et al., 2012) and compared the results with the ones obtained in seroprevalence studies in horses in some other European countries: 0.5–1 % in Sweden, 1.8 % in Greece, 7 % in the Netherlands, 8–23 % in the Czech Republic and 30.7 % in Italy. The authors pointed out that a close comparison among the results is not possible because of the different methods used.

There is currently no standardised validated serological test available that correlates seropositivity to the presence of infectious parasites in the muscles of animals (Kijlstra and Jongert, 2009).

[10] Based also on results of an ANSES funded study that were kindly presented by Dr Radu Blaga during the meeting of the BIOHAZ Working Group on public health hazards to be covered by inspection of meat (bovines) on 4 December 2012.

Furthermore, no standardised reference sera or other reference materials are available and there is no laboratory certification programme (Kijlstra and Jongert, 2008). The only test that can demonstrate the presence of infective *T. gondii* in raw or processed meat is the bioassay in cats and mice, the application of which is limited for both time-related and ethical reasons. The presence of *T. gondii* was demonstrated in meat from experimentally infected horses after inoculation of mice and cats (Al-Khalidi et al., 1980; Alton et al., 1977; Dubey, 1985), as summarised by Tassi (2007). Molecular methods such as polymerase chain reaction (PCR) testing can detect the presence of the genome of the parasite but not its infectiousness. One study looking at the presence of viable cysts in edible tissues of horses slaughtered for human consumption (Al-Khalidi and Dubey, 1979) reported a prevalence of at least 1.4 % (7 out of 500 horses). In the same study it was noted that *T. gondii* was isolated from only 2 of 24 horses with the highest antibody levels in serum. This may reflect either a low number of cysts in those infected horses or a small amount of tissue inoculated into the mice models used. In addition, it may question the association between the antibody level in serum and infectivity, and thus the value of serology, also in light of the fact that *T. gondii* was isolated from cat models inoculated with pooled samples from 128 serologically negative horses. Tenter et al. (2000) indicated that the frequency of *T. gondii* cysts is lower in infected horses than in many other species (pigs, small ruminants, free-range poultry and farmed and wild game). The frequency would be similar to commercially raised poultry but higher than in cattle. It should be noted, however, that scientific studies related to the presence and frequency of *T. gondii* tissue cysts in solipeds are limited.

Horse meat has been identified as a possible source of *T. gondii* infection for humans, but only in four single cases in France (Elbez-Rubinstein et al., 2009; Pomares et al., 2011). The hypothesis is that the horse meat was imported from South America and Canada, and in one case possibly acquired during residence abroad, since the *T. gondii* genotypes isolated from the patients are not circulating in Europe. It is worth mentioning that in both France and Italy horse meat is by tradition also consumed raw.

Highly pathogenic genotypes of *T. gondii* for humans circulate in South America (Dubey et al., 2012). These South American genotypes were detected in the above human toxoplasmosis cases in France, possibly linked to consumption of horse meat, eaten abroad or imported (Elbez-Rubinstein et al., 2009; Pomares et al., 2011). It follows that the importation of live solipeds for slaughter from South America to the EU might result in human infections with highly pathogenic genotypes causing serious disease in newborn children and abortion (Dubey et al., 2012). However, according to the data available,[11] the number of live solipeds imported for slaughter from South America to Europe is extremely limited (18 animals from Argentina in 2002/2003). Even if it is outside the remit of the present opinion, it should be remembered that if the soliped scraps from slaughterhouses, retail soliped meat and domestic meat scraps are not properly destroyed, they may represent a possible route for the introduction of these genotypes in livestock, cats and wild animals in Europe. In summary, it was considered that there is a high degree of uncertainty in the assessment of the priority level for *T. gondii* related to the consumption of soliped meat, and in particular that:

- There are only a few cases of human toxoplasmosis epidemiologically linked to horse meat consumption.
- EU monitoring data for the period 2007–2011 indicates a very low prevalence (0.16 %), but such data originate from a limited number of MSs and an important part of them derive from negative records of routine necroscopic samples submitted to histological examination, the sensitivity of which for the detection of *T. gondii* cysts is known to be extremely low.
- Investigations of equine carcasses for the presence of infectious parasites demonstrated a low prevalence.

[11] EUROSTAT data on imports of live solipeds for slaughter from South American countries (Argentina, Brazil, Chile, Paraguay, Uruguay) to the EU, extraction on 21 March 2013.

- The frequency of *T. gondii* cysts is reported to be lower in infected horses than in many other species.

- Results from serological investigations, which are not yet standardised in solipeds, are characterised by a high variability (from 0 to 90 %), and are not a reliable indicator of the presence of infectious cysts in edible parts of solipeds.

The available data do not allow the assessment of handling, preparation and/or consumption of soliped meat as an important risk factor for human infection with *T. gondii*, nor are they sufficient to definitively establish the priority level for this hazard in soliped meat. It will be necessary to collect more information on the prevalence of *T. gondii* in solipeds to allow such an assessment to be carried out.

- **Due to current controls:** no

Currently no specific control measures for *T. gondii* are applied in solipeds, and the generic hygiene practices in place are not considered to be the reason for the current level of risk related to soliped meat.

2.2.3.6. *Trichinella* spp.

- **Human incidence:** low

Human incidence data for the years 2008–2011 indicate an incidence of 0.05–0.15 cases per 100 000 EU population (Table 6).

According to Murrell and Pozio (2011), 45 615 cases have been documented in the EU MSs from 1986 to 2009. In 2011, 363 cases of human trichinellosis were notified in the EU, of which 268 (73.8 %) were reported as confirmed. Overall, a 20.2 % increase in confirmed cases was recorded in 2011 compared with the previous year. Latvia, Lithuania, Romania, Bulgaria and Slovakia accounted for the majority (84.3 %) of cases in 2011 (EFSA and ECDC, 2013).

- **Severity of disease:** low

The infection in humans can be asymptomatic or develop up to severe symptoms, including death (24 deaths in the WHO European region in a 24-year period). According to human severity data available for the years 2008–2011 (Table 6), one death was reported due to *T. spiralis* in 2011 in Spain (EFSA and ECDC, 2013), following to the consumption of meat from a hunted wild boar.

- **Due to current controls:** yes

The application of the methodology described in Section 2.1.2 (see also decision tree in Figure 1), led to the conclusion that *Trichinella* spp. in soliped meat should be regarded as a low priority hazard, owing to its low notification rate and severity in humans. However, this low priority level was judged to be derived from the current hazard-specific control measures applied at EU level, and in particular from the systematic testing of soliped carcasses for the parasite implemented at the slaughterhouse level in the EU according to meat inspection legislative requirements. Therefore, in agreement with the ranking methodology developed, the hazard is discussed further in the opinion, both with regard to the evidence for soliped meat as an important risk factor for human trichinellosis (here, below), and for possible adaptations of current meat inspection (chapter 5).

In Italy, three large outbreaks of trichinellosis due to the consumption of horse meat occurred from 1975 to 1986 (Table 9). After these unfortunate episodes and the outbreaks that had occurred in France, the Italian Ministry of Health established a process for testing all slaughtered soliped carcasses for the presence of *Trichinella* spp. This control approach identified two *Trichinella* spp. infected horses in 1988 and in 1989. However, this control did not prevent the occurrence of a new very large outbreak of trichinellosis in Italy in 1990. Routine examination permitted the identification of a new

infected horse in 1996 and another one in 1998. Unfortunately, the head of this last *Trichinella* spp. infected horse was by mistake exchanged with the head of a *Trichinella* spp. negative horse and the infected head was placed on the market causing another outbreak of trichinellosis. Subsequently in Italy, other *Trichinella* spp. infected horses were detected in 1998, 2001, 2003 and 2008. Routine *Trichinella* spp. testing did not prevent the occurrence of two further outbreaks in 2000 and 2005. This short review of *Trichinella* spp. testing and control in Italy highlights the role of a strict implementation of *Trichinella* spp. testing in slaughtered soliped carcasses when preventing human outbreaks of trichinellosis. On the other hand, it may also indicate that the implementation of the current testing procedures may allow for a certain number of infected carcasses to remain undetected and enter the food chain. The latter has been suggested as a possibility for pig carcasses by van der Giessen et al. (2013), who investigated the possible origin of a human outbreak of trichinellosis in the Netherlands.

Nematodes of the genus *Trichinella* spp. are circulating in wild animals in most of the MSs of the EU. *Trichinella* spp. has been very rarely detected in pigs in the EU. From 2007 to 2011, only nine MSs reported *Trichinella* spp. findings from pigs, and most of the positive pigs were detected in Romania. In 2011, the highest *Trichinella* spp. prevalences in MSs were reported in farmed wild boars (0.4 %, maximum 0.6 % in Lithuania), hunted wild boars (0.12 %, maximum 1.4 % in Latvia) and other wildlife (e.g. foxes, bears, raccoon dogs). Based on the data reported on food-borne outbreaks in 2011, the sources of the human outbreaks appeared to be pork and wild boar meat (EFSA and ECDC, 2013). The prevalence of infection in wild animals is highly variable from one country to another, according to the environmental conditions, breeding practices, hunters' behaviour, host species composition, etc. (Pozio and Murrell, 2006).

Four *Trichinella* species have been detected in the EU. *Trichinella spiralis* is circulating mainly among domestic and sylvatic swine and among raccoon dogs, whereas it has been rarely detected in the other carnivores (red fox, wolves, mustelids, lynx). This parasite has been detected in 17 MSs. *Trichinella nativa* is circulating mainly among carnivores of Nordic MSs. *Trichinella britovi* is the most widespread species, infecting mainly carnivores and, to a lesser extent, domestic and sylvatic swine. It has been detected in most of the MSs. Finally, *Trichinella pseudospiralis*, the only species infecting both mammals and birds, has been detected in 13 MSs (Merialdi et al., 2011).

Trichinella spp. infections in horses were first documented as early as the late 19th century in experimentally infected horses (Austria) and in a naturally infected horse (Ohio, USA). However, the potential role of horses in the transmission of *Trichinella* spp. to humans was ignored until 1975. Since then horses that were the source of infection for human outbreaks or which were detected as *Trichinella* spp. positive at the slaughterhouse originated from Europe or North America (Liciardi et al., 2009). Globally, from 1975 to 2011, only 34 horses have tested positive for *Trichinella* spp. at the slaughterhouse level (19 horses) or were the source of infection for humans (15 horses). These 34 *Trichinella* spp. infected horses, and in particular the 15 horses that were source of human infection, resulted in 3 334 human cases: 2 296 in France and 1 038 in Italy. In 1985, five persons with trichinellosis died in France. From the data summarised in Table 9 it can be concluded that a *Trichinella* spp. infected horse can be the source of more than 600 infections in humans. It can be also noticed that almost all human infections occurred in France or Italy, probably because in these two countries there is one of the highest consumption levels of soliped meat and in both countries horse meat is by tradition also consumed raw. All the infected horses originated from countries with a high prevalence of *Trichinella* spp. infection in pigs (Serbia, Poland, Romania and Mexico) and/or wildlife (USA and Canada), suggesting that there may be a relationship between the infection in these animals and the infection in horses.

When looking at the official EU monitoring data for the last few years (2007–2011), 3 positive results were reported over a total of 775 532 single samples (0 0004 %), and no positive result from the 23 354 batch samples performed in soliped carcasses (Table 8).

Table 9: *Trichinella* spp. infected horses that were the source of infection for humans or which were identified as *Trichinella* spp. positive at the slaughterhouse (adapted from Liciardi et al. (2009) and Gill (2005)).

Year	Locality (country)	No. of *Trichinella* spp. positive horses (*Trichinella* species)	No. of human infections	Country of horse origin
1975	Bagnolo in Piano (Italy)	1 (*T. britovi)*	89	Former Yugoslavia
1975	Chatenary-Malabry (France)	1 (NA)	125	East Europe
1984	Varese (Italy)	1 (NA)	13	Former Yugoslavia
1985	Paris and Melun (France)	1 (*T. murelli*)	431	Connecticut (USA)
1985	Paris and 10 other foci (France)	1 (*T. spiralis)*	642	Poland
1986	Salsomaggiore (Italy)	1 (*T. britovi)*	300	Former Yugoslavia
1988	Brescia (Italy)	1 (NA)	–	Poland
1989	Brescia (Italy)	1 (NA)	–	Former Yugoslavia
1990	Barletta (Italy)	1 (*T. spiralis)*	500	East Europe
1991	Clermont-Ferrand (France)	1 (NA)	21	USA
1993	Paris and three other foci (France)	1 (*T. spiralis)*	538	Canada
1994	State of Mexico (Mexico)	4 (*T. spiralis)*	–	Mexico
1994	Provence (France)	1 (*T. spiralis)*	7	Mexico
1996	Bordeaux (France)	2 (NA)	–	Poland
1996	Barletta (Italy)	1 (*T. spiralis)*	–	Romania
1998	Haute Garonne (France)	1 (*T. spiralis)*	128	Serbia
1998	Brescia and Piacenza (Italy)	1 (*T. spiralis)*	93	Poland
1998	Toulouse (France)	1 (*T. spiralis)*	404	Serbia
1998	Poggio Imperiale (Italy)	1 (*T. spiralis)*	–	Serbia
1998	France	2 (*T. spiralis)*	–	Serbia
1999	France	1 (*T. spiralis)*	–	Poland
2000	Bitonto (Italy)	1 (*T. spiralis)*	36	Romania or Poland
2001	France	1 (*T. spiralis)*	–	Serbia
2001	Turin (Italy)	1 (*T. spiralis)*	–	Romania
2002	Serbia	1 (*T. spiralis)*	–	Serbia
2003	Turin (Italy)	1 (*T. spiralis)*	–	Serbia
2005	Mantua (Italy)	1 (*T. britovi)*	7	Eastern Europe
2008	Cagliari (Italy)	1 (*T. britovi* and *spiralis)*	–	Poland
2010	Poland	1 (*T. spiralis)*[12]	–	Poland
	Total	34[a]	3 334[b]	

a: 26 horses originated from eastern Europe and 8 horses from North America.
b: 2 296 in France and 1 038 infections in Italy.
NA: *Trichinella* species not available.

Solipeds are thought to acquire *Trichinella* spp. infection in two ways:

- through ingestion of infected flesh from pigs and wild carnivores, possibly as a result of the illegal use of pork or other animal scraps (Murrell et al., 2004; Pozio, 2001);

[12] See: http://www.iss.it/site/Trichinella/index.asp

- through incidental ingestion of feed contaminated by rodent carcasses or of rodent and wild animal carcasses or pork scraps when grazing in pastures (Pozio, 2001).

Observations of the presence of a thin capsule around the larvae in muscle tissues of horses slaughtered in January and of the presence of a thick capsule around the larvae in muscle tissues of horses slaughtered in April and October seems to support the hypothesis that horses acquire the *Trichinella* spp. infection in late autumn or winter, i.e. the period of the year when most of fattening pigs are slaughtered at home or during the hunting season (Pozio, 2001) stressing the link between *Trichinella* spp. infections in backyard and free-range pigs and horses. However, direct transmission to solipeds through pork scraps has never been demonstrated, and many uncertainties remain about the pathway(s) for acquiring *Trichinella* spp. infection in solipeds. In addition, the extent to which feeding solipeds with pork scraps, which remains an illegal practice in the EU, is practised is unknown.

Unlike most of the natural *Trichinella* spp. hosts, in which there is a cumulative infection level related to the host age, a cumulative effect was documented only in one horse in which two *Trichinella* species (*T. britovi* and *T. spiralis*) were detected (Liciardi et al., 2009).

The only available method for diagnosing *Trichinella* spp. infection in solipeds is the artificial digestion carried out according to one of the methods reported in Regulation (EC) No 2075/2005. The serological diagnosis is not an acceptable method to detect or monitor this infection in solipeds, since 3–6 months after infection, anti-*Trichinella* spp. antibodies disappear in sera, although there are still infective larvae in the muscles (Boireau et al., 2000; Hill et al., 2007b; Pozio et al., 1997; Soulé et al., 1989).

To further qualify the concerns related to *Trichinella* spp. and handling, preparation and consumption of soliped meat, and considering that:

- consumption of horse meat, which in some regions is often consumed raw, is a risk factor for very large outbreaks of human trichinellosis;
- EU monitoring data indicate an extremely low prevalence (< 0.0004 %);
- the frequency of *Trichinella* spp. larvae is believed to be lower in horses compared to other species such as pigs and wild boars;
- results from serology are not indicative of the presence of *Trichinella* spp. larvae because anti-*Trichinella* spp. antibodies disappear even if infectious *Trichinella* spp. larvae are still present in the muscles;
- it is expected that a very high number of human cases would originate from a single infected soliped carcass;

it is concluded that *Trichinella* spp. in soliped meat is a low-frequency infection with a potential high human risk (Boireau et al., 2000).

2.2.4. Summary results of the priority ranking

Table 10 indicates the criteria used to provide replies to the questions posed by the decision tree and reports the results of the prioritisation of the hazards in soliped carcasses.

Table 10: Priority ranking of hazards according to the categorisation in the decision tree presented in Figure 1.

Hazard	**Notification rate in humans** (High: ≥ 10/100 000)	**Severity (% deaths over confirmed cases)** (High: ≥ 0.1 % in more than one year)	**Evidence for meat from domestic solipeds as an important risk factor** (see section 2.3.2)	**Priority**	**Low priority 'low' due to current controls**
Bacillus anthracis	Low	High	No	Low	No
Pathogenic VTEC	Low	High	No	Low	No
Salmonella spp. (including ESBL/AmpC gene-carrying *Salmonella* spp.)	High	–	No	Low	No
Yersinia enterocolitica	Low	Low	–	Low	No
Toxoplasma gondii	Low	High	Undetermined	Undetermined	No
Trichinella spp.	Low	Low	–	Low	Yes

– Not to be evaluated according to the decision tree.

2.3. Conclusions and recommendations

- Identification and priority ranking of the main risks for public health that should be addressed by soliped meat inspection was hampered by the lack of animal and carcass surveillance and epidemiological data.

- According to the decision tree developed, and based on the limited data available, the identified soliped meat-borne biological hazards were categorised as follows:

    - *Trichinella* spp. was assessed as a hazard of low priority with regard to soliped meat inspection. However, this low priority level was judged to be derived from the current hazard-specific control measures applied at the EU level, and in particular from the systematic testing of soliped carcasses for the parasite implemented at the slaughterhouse level in the EU according to meat inspection legislative requirements. Therefore, in agreement with the ranking methodology developed, meat inspection-related aspects of *Trichinella* spp. are discussed further in the opinion.

    - *T. gondii* was not classified in terms of priority with regard to soliped meat inspection because of insufficient data.

    - *B. anthracis*, pathogenic VTEC, *Salmonella* spp. (including ESBL/AmpC gene-carrying *Salmonella* spp.) and *Y. enterocolitica* were classified as hazards of low priority with regard to soliped meat inspection. This low priority level was judged not to be derived from the current hazard-specific control measures applied at the EU level.

- Because the hazard identification and ranking relates to the EU as a whole, refinements reflecting differences among regions or production systems are recommended if/where hazard monitoring indicates.

- Furthermore, as new hazards might emerge and/or hazards that at present are not a priority might become more relevant over time or in some regions, both hazard identification and the ranking are to be revisited regularly to reflect this dynamic epidemiological situation.

- Insufficient/lack of data and related assessment uncertainties were issues in the priority ranking exercise in this opinion. This was particularly relevant for *T. gondii*, for which it was impossible to reach a definitive conclusion about the priority ranking. Hence, it is recommended that data on the occurrence of viable *T. gondii* tissue cysts are collected.

- In order to improve future ranking exercises it is imperative that harmonised data are collected on:

    - the incidence and severity of human diseases caused by relevant hazards;

    - source attribution;

    - the identification and ranking of emerging hazards that could be transmitted through handling, preparation and consumption of soliped meat.

3. Assessment of strengths and weaknesses of current meat inspection methodology

3.1. General background

Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption, including meat. According to this Regulation, meat inspection tasks are regulated in the following stages:

- FCI;
- *ante-mortem* inspection;
- animal welfare;
- *post-mortem* inspection;
- specified risk material and other animal by-products;
- laboratory testing.

This chapter discusses the main requirements, strengths and weaknesses related to the collection and analysis of FCI, *ante-mortem* and *post-mortem* inspection and some of the connected laboratory testing.

Information gathered from stakeholders (EFSA, 2012) indicates that solipeds are sent to slaughterhouses both individually and in batches and may be slaughtered in both dedicated slaughterhouses and plants used for slaughtering other species. In the latter, animals of the different species may be slaughtered on the same day. Mission reports of the Food and Veterinary Office (FVO) of the European Commission indicate that no specialised soliped slaughterhouses exist in some countries, where solipeds are slaughtered in bovine plants.[13] When comparing the slaughter process for different species of solipeds (horses vs. donkeys) and of solipeds with bovines, it is expected that there will be no major differences and the processes will be similar (EFSA, 2012).

3.2. Food chain information

3.2.1. Description

According to Regulation (EC) No 854/2004, the official veterinarian has to take into consideration any pertinent information on the food chain (e.g. from the records of the holding of provenance of animals intended for slaughter, official certificates accompanying the animals, declarations by veterinary practitioners and official and approved veterinarians carrying out controls during primary production, as well as documentation from the voluntary quality control systems of operators). According to Regulation (EC) No 853/2004, slaughterhouse operators must be provided with the FCI no less than 24 hours before the arrival of animals at the slaughterhouse. However, competent authorities may allow that FCI is delivered to the abattoir concurrently with the animals to be slaughtered, as long as such procedures do not jeopardise the objectives of the Regulation.

Specifically, the relevant FCI is to cover:

- the status of the holding of provenance or the regional animal health status;
- the animals' health status;

[13] FVO mission report 2011-6021 (see: http://ec.europa.eu/food/fvo/ir_search_en.cfm).

- veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods;
- the occurrence of diseases that may affect the safety of meat;
- the results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat, including samples taken in the framework of the monitoring and control of zoonoses and residues;
- relevant reports about previous *ante*- and *post-mortem* inspections of animals from the same holding of provenance including, in particular, reports from the official veterinarian;
- production data, when this might indicate the presence of disease; and
- the name and address of the private veterinarian normally attending the holding of provenance.

The producer may not be required to provide some of the above information when this is already made available by other means, such as, for example, through a standing arrangement or a quality assurance scheme.

Food business operators must check passports accompanying domestic solipeds to ensure that the animal is acceptable for slaughter. If they accept the animal for slaughter, they must give the passport to the official veterinarian.

According to EU legislation (Regulation (EC) No 504/2008), solipeds need to be identified by means of a single lifetime identification document, also called passport, which should be unequivocally linked to the animal. Such an identification document, issued by relevant national bodies for both animals born in the EU and imported animals, shall in principle accompany the animals during all movements, with some derogations. In particular, the passport shall accompany all solipeds when they are transported to the slaughterhouse. An exception to this provision is allowed for foals younger than 12 months when they are sent directly from the holding of birth to the slaughterhouse and provided that some additional conditions are ensured, such as an uninterrupted traceability from the holding of origin to the slaughterhouse and an individual identification during the transport, which should be also mentioned within the FCI.

Information to be included in the passport mainly relates to the identity of the soliped and its health status, including vaccinations and laboratory health tests performed. In addition, information related to certain medical treatments, which require a withdrawal period before being submitted to slaughter have to be reported in the passport for all animals that may be intended for slaughter. Those treatments do not need to be reported in cases in which the owner/keeper of the animal irreversibly decides that the animal is not intended for slaughter. In this case the decision has to be also clearly reported in the passport and the animal will never be allowed to enter the food chain.

3.2.2. Strengths

FCI related to individual identification of animals is a prerequisite for the implementation of a traceability system further along the food chain. Also, consideration of FCI is useful for the differentiation between solipeds coming from integrated and non-integrated production systems. The concept of integrated production systems for meat-producing animals (SCVMRPH, 2001) requires that it is operated in an integrated manner from birth through the rearing phase to slaughter, with all the relevant data transferred backwards and forwards between the farm and the abattoir. Information that must be available in an integrated system includes animal-associated criteria, good farming practice

(GFP) criteria, production system-related criteria and records including documentation of animal movements, medical records, etc.

In the current EU legislation related to meat inspection a definition of integrated system is not explicitly stated, but essential animal-related food safety information that must be available is listed (see Section 3.2.1).

In the current meat inspection system for solipeds, the particular relevance of FCI is in respect of some specific infections/diseases in solipeds that could affect soliped meat safety. Among specific diseases in solipeds, particular relevance would have the ones that are transmissible to humans (e.g. glanders, strangles). In principle, where available and complete, FCI enables risk differentiation of solipeds or batches of solipeds as a basis for decisions to pay particular attention to higher risk solipeds or batches of solipeds during *ante-* and *post-mortem* examinations and to apply specific measures to ensure meat safety.

3.2.3. Weaknesses

Information on the use of FCI within the meat inspection system for solipeds is scarce and largely anecdotal. It does not include any information on the carriage of asymptomatic zoonoses that can be carried/faecally shed by healthy animals resulting in carcass contamination. According to stakeholders, it seems that in practice the information provided with solipeds sent to slaughter is usually limited, and mainly includes data on medical treatments (EFSA, 2012). A number of mission reports of the FVO of the European Commission in MSs, evaluating several aspects related to the slaughter of equine animals, identified a number of shortcomings in the implementation of the requirements on FCI.[14]

In solipeds the legal requirements in terms of traceability are different and less stringent than in other species, cattle in particular. Regulation (EC) No 504/2008 regulates the methods for the identification of solipeds, but it does not require a system for data recording, in contrast to what is foreseen for cattle (Regulation (EC) No 1760/2000) and small ruminants (Regulation (EC) No 21/2004).

The solipeds identification system is based on a single lifetime identification document, on the link between the document and the animal, and on a database managed by the bodies issuing the identification document. Traceability is based on the link between the animal and the identification document, which has to follow the animal in all its movements and, for slaughter animals, must be part of the FCI that arrives at the slaughterhouse together with the animals. The database is updated only following a change in the ownership of the animal, or when the animal dies or is slaughtered, and the set of information associated to the animals does not compulsorily contain the reference to the holding where the animal was born and kept. It is not required that the movements of the animals are recorded in the database. Such rules give guarantees about the ownership of the animal, but do not provide all the elements needed to guarantee the full traceability of movements among different farms. Moreover, the electronic identification of Equidae is compulsory for animals born after 1 January 2009, while animals born before this date can be identified only through a paper passport, which gives less guarantee of a unique link with the animal. The electronic identification system in solipeds consists of a microchip, usually handled by veterinarians of the breeding associations or official veterinarians and inoculated into the neck of the animals. The microchip contains the unique equine life number (UELN), and the microchip number can be linked to a central database and/or to the passport. Leadon et al. (2012) indicate that, despite legal requirements in terms of identification and possession of a passport, compliance with legislation is poor.

[14] FVO mission reports 2007-7373, 2010-8501, 2011-6021 (see: http://ec.europa.eu/food/fvo/ir_search_en.cfm).

3.3. *Ante-mortem* inspection

3.3.1. Description

Ante-mortem inspection is carried out according to Regulation (EC) No 854/2004. The principles apply to all animal species and no specific requirements are foreseen for solipeds. At the abattoir, all solipeds presented for slaughter are subjected to *ante-mortem* inspection. The inspection must be conducted within 24 hours of arrival at slaughterhouse and less than 24 hours before slaughter, and can be carried out by the official veterinarian at any additional time. Exceptions include emergency slaughter outside the slaughterhouse. The primary objective of *ante-mortem* inspection is to determine if animal welfare is compromised, or animal/zoonotic diseases prevail. In addition to regular *ante-mortem* inspection, a clinical examination must be carried out in those cases where the operator or the official auxiliary has put aside slaughter animals.

According to stakeholders (EFSA, 2012), typical findings at *ante-mortem* inspection and the main reasons for condemnation are linked to injured animals, respiratory syndromes, and welfare problems.

3.3.2. Strengths

The strengths of *ante-mortem* examination are particularly related to animal welfare and animal health aspects, which are not dealt with in this chapter. The main strength of *ante-mortem* examination from the public health perspective is that its findings (particularly in combination with FCI) can be the basis for key decisions relative to: whether animals can progress to slaughter normally or will require to be separated from the normal line; which animals must be expelled from the food chain; and which animals need more detailed *post-mortem* examination.

Animals submitted as casualty or emergency slaughter cases are normally subjected to individual and careful *ante-mortem* examination as they may pose an increased risk with respect to public health hazards including food-borne, and may be directed to more detailed *post-mortem* examination including laboratory testing. Solipeds suffering from acute septicaemia and those showing evidence of fever due to other causes are identified as unfit for slaughter at *ante-mortem* examination.

Furthermore, EU regulation (Regulation (EC) No 853/2004) requires that 'animals must be clean' when presented for slaughter in abattoirs, because it has been recognised (although primarily for ruminants) that skins are contaminated with microbial pathogens and serve as one of the key sources for microbial carcass contamination at the slaughter line. *Ante-mortem* examination can be used as a means of detecting visible faecal contamination of the skin, which is relevant for possible cross-contamination of the resultant meat.

3.3.3. Weaknesses

Usually, live solipeds are visually examined in groups and only those showing obvious clinical manifestations, lesions and/or abnormal behaviour are subjected to more detailed examination. Nevertheless, even solipeds not showing any clinical manifestations, lesions and/or abnormal behaviours at *ante-mortem* examination may have subclinical diseases or infections of public health relevance (e.g. trichinellosis). Furthermore, even healthy solipeds may faecally carry/shed bacterial and parasitic food-borne pathogens, which *ante-mortem* examination cannot reveal.

There is no information available that *ante-mortem* assessment of the visual cleanliness of solipeds is routinely applied in practice, even though stakeholders reported that over recent years more attention has been given to the cleanliness of animals at slaughter (EFSA, 2012).

3.4. *Post-mortem* inspection

3.4.1. Description

Post-mortem examination of slaughtered solipeds is conducted macroscopically (visual and by palpation and incision) on the slaughter line at multiple inspection points for the head and pluck (organs of thoracic cavity), abdominal organs, carcass as it undergoes dressing, and final carcass inspection prior to health marking. It is carried out according to Regulation (EC) No 854/2004:

- Visual inspection of the head and, after freeing the tongue, the throat. Palpation and, if necessary, incision of the submaxillary, retropharyngeal and parotid lymph nodes (lymph nodes retropharyngiales, mandibulares and parotidei). The tongue must be freed to permit a detailed visual inspection and palpation. The mouth and the fauces must be visually examined and palpated.

- Where appropriate,[15] solipeds are to be examined for glanders. Examination for glanders in solipeds is to include a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum.

- Visual inspection of the lungs, trachea and oesophagus. Palpation of the lungs. Palpation and, if necessary, incision of the bronchial and mediastinal lymph nodes (lymph nodes bifucationes, eparteriales and mediastinales). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption.

- Visual inspection of the pericardium and the heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum.

- Visual inspection of the diaphragm.

- Visual inspection, palpation and, if necessary, incision of the liver and the hepatic lymph nodes (lymph nodes portales).

- Visual inspection of the gastrointestinal tract, the mesentery and the gastric and mesenteric lymph nodes (lymph nodes gastrici, mesenterici, craniales and caudales); incision, if necessary, of the gastric and mesenteric lymph nodes.

- Visual inspection and, if necessary, palpation of the spleen.

- Visual inspection and palpation of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (lymph nodes renales).

- Visual inspection of the pleura and peritoneum.

- Visual inspection of the genital organs of stallions (except for the penis, if already discarded) and mares.

- Visual inspection of the udder and its lymph nodes (lymph nodes supramammarii) and, if necessary, incision of the supramammary lymph nodes.

[15] An example would be when solipeds originate from a country/region where the disease is present.

- Visual inspection and palpation of the umbilical region and joints of young animals. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined.

- All grey or white horses must be inspected for melanosis and melanomas by examination of the muscles and lymph nodes (lymph nodes subrhomboidei) of the shoulders beneath the scapular cartilage after loosening the attachment of one shoulder. The kidneys must be exposed and examined by incision through the entire kidney.

According to Commission Regulation (EC) No 2075/2005, laying down specific rules on official controls for *Trichinella* spp. in meat, all carcasses of solipeds shall be systematically sampled in slaughterhouses as part of the *post-mortem* examination. A sample shall be collected from each carcass and the sample shall be examined in accordance with specified methods in a laboratory designated by the competent authority.

Some specific prescriptions apply to the examination of meat from domestic solipeds compared with swine. In particular:

- Specimens weighing at least 10 g should be taken from the lingual or jaw muscle.

- Where those muscles are lacking, a larger-sized specimen is to be taken from a pillar of the diaphragm, clean of connective tissue and fat, at the transition to the sinewy part.

- At least 5 g of sample is to be digested following the specified reference methods of detection (magnetic stirrer method for pooled sample digestion, mechanically assisted pooled sample digestion method (sedimentation and on-filter isolation techniques), automatic digestion method).

- The maximum total weight of muscle examined for each digest, depending on the specified reference methods, and the maximum digestion time are also prescribed.

During *post-mortem* inspection of slaughtered solipeds, various lesions can be observed, including among others those indicated in Tables 11 and 12. According to stakeholders (EFSA, 2012), typical findings and reasons for condemnation at *post-mortem* inspection are often linked to poor nutritional status, metabolic and neoplastic conditions and acute conditions in which septicaemia is suspected.

3.4.2. Strengths

As in the case of *ante-mortem* inspection, the strengths of *post-mortem* examination of solipeds are particularly related to animal welfare and animal health aspects, which are not dealt with in this chapter. These aspects include detection of specific animal diseases (i.e. non-zoonotic and/or non-food-borne) or meat quality-related abnormalities such as bruising, which are primarily indicators of welfare problems.

Some zoonotic diseases (e.g. glanders, brucellosis, strangles) can be detected by *post-mortem* examination (Table 11). However, modern systems of animal husbandry, disease control and animal health care have considerably reduced the occurrence of these diseases in the EU. Hence, the ability of current *post-mortem* examination to macroscopically detect such diseases is relevant only for animals coming from/in regions where they are present. Furthermore, there is no evidence of their meat-borne transmission, so their detection at *post-mortem* inspection relates to occupational risk rather than to meat-borne risk.

Septicaemia, caused by various pathogenic microorganisms in the blood e.g. *Streptococcus* spp., *Salmonella* spp., pathogenic *E. coli* (Table 12) always results in an acute, systemic and serious condition, which it is expected will be detected before slaughter (on farm or at *ante-mortem* inspection

of solipeds). In the chronic phase of septicaemia the condition may result in the formation of abscesses (pyaemia), which are detectable only at *post-mortem* examination. However, septicaemia-causing organisms, even those that are zoonotic, are often non-meat-borne (e.g. *Streptococcus* spp.). Under abattoir conditions using routine inspection methods, it is not possible to differentiate the organisms causing septicaemia, i.e. whether they are zoonotic and they have a meat-borne or non-meat-borne transmission route to humans (hence any carcass with lesions suspected of indicating septicaemia is condemned).

Post-mortem inspection of solipeds also includes laboratory examination of muscle samples for the presence of the zoonotic and meat-borne parasite *Trichinella* spp., and the related method (Section 3.4.1) is currently considered reliable and sufficiently sensitive.

Finally, similarly to *ante-mortem* inspection of the skin, *post-mortem* inspection allows the detection of visible faecal contamination of dressed carcasses, which is relevant for potential cross-contamination of the meat.

3.4.3. Weaknesses

The majority of gross lesions that can be detected by macroscopic examination are of animal health and/or meat quality relevance, and do not pose a serious threat to public health (Tables 11 and 12). These include, for example, lesions that are caused by non-zoonotic agents (e.g. orbivirus, equine lentivirus, *Trypanosoma equiperdum*) or by zoonotic agents that are not transmissible via the meat-borne route (e.g. *Rhodococcus equi, Actinobacillus equuili, B. abortus, Echinococcus*), or are metabolic (e.g. cachexia). Therefore, it is considered that the actual effectiveness of routine macroscopic *post-mortem* examination in detecting lesions relevant for public health and, particularly, hazards that are food-borne via meat consumption (i.e. meat-borne) is limited.

Furthermore, some conditions (e.g. some cases of enteritis, septicaemia, bone lesions) can be caused by or contain meat-borne hazards, but the hazards cannot be differentiated from other non-meat-borne hazards causing similar conditions, i.e. cannot be identified macroscopically at *post-mortem* inspection but only in the laboratory.

On the other hand, a number of zoonotic biological hazards can be present in slaughtered solipeds, but are not associated with any macroscopically detectable condition and so are undetectable by current *post-mortem* meat inspection and might be meat-borne. Although not considered of high priority in relation to soliped meat safety, such hazards may be faecally excreted by non-clinically diseased solipeds and consequently transferred on the carcasses during slaughterline operations, their control relies on prevention of faecal contamination and cross-contamination of meat. Therefore, with respect to the macroscopically undetectable biological hazards, current *post-mortem* inspection of solipeds actually does not contribute to prevention of corresponding human food-borne disease. Consequently, control measures for those hazards at the abattoir that are aimed at reducing the human food-borne risks via soliped meat are based on optimisation of process hygiene managed through GMP/GHP and HACCP system principles (‘owned’ and implemented by the operator), rather than on official *post-mortem* meat inspection *per se*.

Any manual manipulation of meat/organs of slaughtered solipeds, including palpation/incision conducted to detect macroscopic lesions during *post-mortem* inspection, may lead to cross-contamination with microbial hazards present on their surfaces or inside (e.g. in lymph nodes). Such cross-contamination can occur between different parts of the same animal as well as between animals consecutively inspected on the slaughter line. In itself, based on the fundamental principles of food hygiene, any cross-contamination is undesirable, so this is a potential weakness of *post-mortem* meat inspection. Although outside the scope of this opinion, consideration should be also given to the potential occupational risks posed. For example, in the case of solipeds suspect for glanders, splitting of the head may represent a relevant occupational risk.

With respect to muscle sampling of each slaughtered soliped for laboratory testing for *Trichinella* spp., which is a part of *post-mortem* meat inspection, manual handling involves only a single anatomical site and it is in practice usually not conducted by meat inspectors. Although it can be considered that the risk of sampling-mediated microbial cross-contamination is, therefore, lower than the risk of cross-contamination mediated by other manual meat inspection procedures, it still cannot be excluded. To reduce the risk to a minimum, staff needs to be properly trained to use a standardised minimum-handling sampling technique with appropriate between-sample sanitation of hands and any tools used.

As is the case for meat inspection in other species, judgement of the fitness of soliped meat for human consumption during the current *post-mortem* inspection is based on the identification of 'conditions making meat unfit for human consumption' but does not make a clear distinction in terms of food-borne risk between different subcategories, i.e. between non-zoonotic conditions making meat unfit (inedible) on aesthetic/meat quality grounds (e.g. repulsive/unpleasant appearance or odour), non-zoonotic conditions making meat unfit in order to prevent the spread of animal diseases, zoonotic conditions making meat unfit owing to their transmissibility to humans via the meat-borne route (e.g. *Trichinella* spp.), and zoonotic conditions making meat unfit owing to their transmissibility via routes other than meat-borne (e.g. *R. equi*).

Table 11: Examples of frequent soliped-related diseases observed at *post-mortem* inspection (adapted/combined from AA.VV. (2010), Herenda et al. (1994b), Radostis et al. (1994), Stromberg (2012)[16], Weese (2002)). Metabolic and other non-infectious diseases are not included.

Disease	Lesions	Causative agent	Meat-borne transmission from solipeds to humans through the gastrointestinal tract	Transmission from solipeds to humans via other routes
African horse sickness	Intermuscular and subcutaneous oedema and haemorrhage. Enlarged lymph nodes. Trachea/bronchi filled with frothy fluid. Pleural exudate and pulmonary oedema. Hydrothorax and ascites. Petechial haemorrhages on heart, pericardium, intestinal serosa and kidneys	*Orbivirus*	No	No
Equine infectious anaemia	Subcutaneous oedema on legs and abdomen. Anaemia. Icterus. Subserosal haemorrhage. Hydrothorax and ascites. Enlarged spleen and liver. Enlarged, oedematous and haemorrhagic kidneys. Emaciation	*Lentivirus*	No	No
Equine encephalomyelitis	Gross lesions usually lacking	Arboviruses	No	No
Contagious equine metritis	Suppurative vaginitis, cervicitis and endometritis	*Taylorella equigenitalis*	No	No
Tetanus	Gross lesions usually lacking	*Clostridium tetani*	No	No
Glanders	Pyogranulomatous, ulcerating dermatitis and of the respiratory mucosal membranes. Pyogranulomatous, nodular pneumonia. Haematogenous spread to internal organs, especially the spleen	*Burkholderia mallei*	No	Yes
Strangles	Purulent sinusitis, guttural pouch empyema. Purulent lymphadenitis (abscesses in lymph nodes) of the head and mesenterium. Metastatic abscesses in liver, kidneys, brain and other internal organs together with purulent pleuritis and peritonitis	*Streptococcus equi*	No	Yes
Dourine equine trypanosomiasis	No specific lesions. Oedema of genitalia, perineum and ventral abdomen together with fluid in pleural, pericardial and peritoneal cavities. Emaciation, anaemia and characteristic depigmentation of dermal scars (‘urticarial-like plaques’) on the external genitals	*Trypanosoma equiperdum*	No	No

[16] See: www.cldavis.org/cgi-bin/download.cgi?pid=168

Table 12: Examples of macroscopic lesions observed at *post-mortem* inspection of solipeds (adapted/combined from AA.VV. (2010), Herenda et al. (1994b), Radostis et al. (1994), Stromberg (2012)[17], Weese (2002)). Metabolic and other non-infectious diseases are not included.

Organ/system	Lesions	Associated causative agents	Meat-borne transmission from solipeds to humans through the gastrointestinal tract	Transmission from solipeds to humans via other routes
Respiratory system	Suppurative rhinitis	*Streptococcus equi*	No	Yes
	Granulomatous pneumonia	*Burkholderia mallei*	No	Yes
	Abscesses in lungs	*Rhodococcus equi*	No	Yes
		Staphylococcus aureus	No	Yes
		Burkholderia pseudomallei	No	Yes
	Fibrinous tracheitis	Equid herpesvirus 4	No	No
		Equine arteritis virus	No	No
		Equine influenza virus	No	No
	Fibrinous pleuritis	*Escherichia coli*	Yes[ab]	No
Liver	Disseminated, miliary hepatic necrosis/granulomatous hepatitis	*Salmonella* spp.	Yes[b]	No
	Disseminated hepatic necrosis	*Escherichia coli*	Yes[ab]	No
	Diffuse hepatic necrosis	*Clostridium piliforme*	No	No
	Hydatid cysts	*Echinococcus equinus, E. granulosus*	No	No
Kidney	Apostematous nephritis	*Actinobacillus equuli*	No	Yes
Gastrointestinal system	Gastritis	*Gasterophilus intestinalis, G. nasalis*	No	No
		Draschia megastoma	No	No
		Habronema microstoma, H. muscae	No	No
	Multifocal gastric epithelial hyperplasia	*Trichostrongylus axei*	No	No
	Haemomelasma ilei	*Strongylus* spp. larvae	No	No
	Catarrhal and fibrinous enteritis in small intestine	*Salmonella* spp.	Yes[b]	No
		Paranoplocephala mammilana	No	No
		Parascaris equorum	No	No

[17] See: www.cldavis.org/cgi-bin/download.cgi?pid=168

Organ/system	Lesions	Associated causative agents	Meat-borne transmission from solipeds to humans through the gastrointestinal tract	Transmission from solipeds to humans via other routes
	Catarrhal, haemorrhagic and necrotising typhlocolitis	*Salmonella* spp.	Yes[b]	No
		Clostridium difficile	No	No
		Anoplocephala perfoliata	No	No
		Strongylus vulgaris	No	No
		Setaria equi	No	No
		Strongyloides	No	No
		Cyathostominae	No	No
	Multifocal mural abscesses and suppurative lymphadenitis	*Streptococcus equi* subsp.	No	Yes
		zooepidemicus	No	Yes
		Rhodococcus equi		
Musculoskeletal system	Arthritis	*Brucella abortus*	No	Yes
		Actinomyces bovis	No	Yes
		Escherichia coli	Yes[ab]	No
		Staphylococcus aureus	No	Yes
	Osteomyelitis	*Salmonella* spp.	Yes[b]	No
		Corynebacterium spp.	No	No
		Streptococcus spp.	No	Yes
		Staphylococcus aureus	No	Yes
	Emphysematous and necrotising myositis	*Clostridium novyi*	No	No
		Clostridium septicum	No	No
		Clostridium chauvoei	No	No
Skin	Alopecia and depigmentation (onchocerciasis)	*Onchocerca cervicalis*	No	No[c]
	Pyogranulomatous, ulcerating dermatitis	*Burkholderia mallei*	No	Yes
	Pyogranulomatous dermatitis (botryomycosis)	*Staphylococcus aureus*	No	Yes
	Warts	Equine papillomavirus	No	No
	Sarcoids	Bovine papillomavirus	No	No[d]

a: For some human pathogenic groups.
b: The agent is categorised as of low priority with regard to soliped meat inspection by the assessment performed in this Opinion.
c: Only through vectors.
d: Yes from bovines, no evidence from equines.

3.5. Conclusions and recommendations

The strengths and weaknesses of the current meat inspection were assessed only in relation to soliped meat safety from a public health perspective.

- Strengths:
  - In principle, utilising FCI to better focus *ante-mortem* and/or *post-mortem* meat inspection is beneficial.
  - *Ante-mortem* inspection enables the detection of clinically observable zoonotic diseases, animal identification enabling traceability and visual evaluation of the cleanliness of animals.
  - *Post-mortem* inspection enables the detection of macroscopic lesions associated with some biological hazards causing zoonotic diseases, e.g. glanders and strangles (non-meat-borne), as well as detection of *Trichinella* spp. by laboratory examination.
  - *Ante-mortem* and *post-mortem* inspection detect visible faecal contamination of the skin and dressed carcasses, which is relevant for potential cross-contamination of the meat.
- Weaknesses:
  - The current soliped traceability system does not include compulsory recording in databases of all movements of solipeds from birth to slaughter.
  - Currently FCI is used only to a limited extent and does not include sufficient data to classify solipeds in relation to the meat safety risk associated with the handling, preparation and consumption of soliped meat.
  - There is no evidence to suggest that *ante-mortem* visual assessment of the cleanliness of solipeds is routinely applied in practice.
  - Manual handling of meat, including the use of palpation/incision techniques during *post-mortem* inspection aimed at the detection of some non-zoonotic and/or zoonotic but non-meat-borne hazards, mediates cross-contamination. It does not contribute to the detection of relevant hazards, i.e. *Trichinella* spp. Hence, these two opposing effects of palpation/incision have to be considered carefully to ensure an overall benefit for public health. To a lesser extent, such cross-contamination concerns may also be related to manual sampling for *Trichinella* spp. testing.
  - Microbial agents associated with common pathological conditions detected at *post-mortem* inspection of solipeds (e.g. pneumonia, abscesses) are caused by non-zoonotic and/or zoonotic hazards, and the latter generally pose an occupational rather than a food-borne risk.
  - Judgement of the fitness of meat for human consumption in current *post-mortem* inspection does not differentiate food safety aspects (related to the spread of soliped meat-borne hazards through the food chain) from meat quality aspects, prevention of animal diseases and occupational hazards.
- Traceability (identification and movements) systems for solipeds intended for slaughter should be improved in order to improve the FCI in relation to their origin and movements throughout their life.

- The development and implementation of a harmonised FCI data collection and analysis system for the main hazards in solipeds at both the farm and the abattoir level are recommended.

4. Recommended new inspection methods for hazards not currently addressed by meat inspection

On the basis of the prioritisation exercise carried out according to the methodology described in Chapter 2, a number of hazards were initially identified as possibly transmitted to humans through soliped meat, with a risk linked to the pre-chilling stages. For almost all of these hazards (*B. anthracis*, pathogenic VTEC, *Salmonella* spp. including ESBL/AmpC gene-carrying *Salmonella* spp., *Y. enterocolitica* and *T. gondii*) it is considered that meat inspection as prescribed by current legislation does not allow their detection on the basis of *ante-mortem* and *post-mortem* inspection. However, all these hazards were categorised as of low or undetermined (*T. gondii*) priority. Therefore no specific amendments to the current meat inspection methodology are discussed or recommended. With regard to *T. gondii*, some additional information in relation to possible control options and potential implications for meat inspection are discussed below, although the current categorisation does not justify recommendations for new inspection methods to be drawn up at present.

Solipeds can acquire *T. gondii* in two different ways: (i) by the ingestion of oocysts shed in cat faeces and contamination of the feed; or (ii) by the ingestion of feed containing raw product of animal origin. Even if the second means of transmission can be avoided by strict control of feed, it is extremely difficult to avoid the first means of transmission because the oocysts are very resistant in the environment and they can stick to the boots of farm workers and to the wheels of agricultural vehicles and other fomites, and thus can be transported anywhere and ingested by solipeds. Furthermore, solipeds always have outdoor access, which rules out the categorisation of animals according to their breeding system.

With regard to categorising animals sent for slaughter in terms of their potential *Toxoplasma* risk by serological testing of individual animals, as discussed in Section 2.2.3.5, it should be noted that not necessarily all solipeds serologically positive for *T. gondii* are carriers of infectious cysts in their muscles or other edible tissues. In addition, the identification of solipeds that are carriers of infectious *T. gondii* tissue cysts is virtually impossible at the slaughterhouse, because the tissue cysts are not widespread in all muscles or other tissues, as for instance *Trichinella* spp. larvae are, and, even if there are preferential tissues such as the heart muscles or brain, the lack of tissue cysts in these locations does not prevent the presence of cysts in other sites of soliped carcasses. On the other side, limited information is available in literature with regard to the presence of cysts in sero-negative animals. Al-Khalidi and Dubey (1979) isolated *T. gondii* from cat models inoculated with pooled samples from 128 serologically negative horses. As mentioned earlier in this opinion, no standardised reference sera or other reference materials are available to carry out *T. gondii* serological testing in solipeds, as well as in other livestock species.

The only way to prevent the risk of *T. gondii* transmission to consumers would be the inactivation of *T. gondii* tissue cysts by freezing, cooking or irradiation. *T. gondii* tissue cysts were rendered non-viable when internal temperatures reached 67 °C or –12 °C, and freezing meat for one day in a household freezer rendered tissue cysts non-viable (Dubey, 1988). Microwaving does not kill all *T. gondii* because of uneven cooking (Lundén and Uggla, 1992). *T. gondii* tissue cysts can be rendered non-viable by irradiation at doses of 0.5 kGy (Dubey et al., 1986). The strain of *T. gondii* was reported to have no effect on the killing of tissue cysts by irradiation under defined conditions (Dubey, 1996). Even though the above studies were not performed on soliped meat, it is assumed that the sensitivity of *T. gondii* cysts in soliped meat would be similar to that in meat from other species, since no differences were observed between *T. gondii* tissue cysts in meat of other livestock species (e.g. sheep, pig).

5. Recommended adaptation of methods that provide an equivalent protection for current hazards

Trichinella spp. was categorised as of low priority in the assessment. However, this was considered to be the result of the current hazard-specific control measures applied (i.e. testing of all soliped carcasses). Therefore, the possible adaptation of methods that provide an equivalent public health protection for *Trichinella* spp. are discussed in this chapter. In addition, recommendations for adaptation of other aspects of current meat inspection practices are also formulated.

5.1. Principles of risk-based meat safety assurance system to control *Trichinella* spp. in soliped meat

Direct identification of *Trichinella* spp. larvae in soliped muscles—those in which the largest number is expected (predilection sites) including tongue, masseter or, if missing, diaphragm—is possible only during *post-mortem* inspection of carcasses. The current examination method for the detection of *Trichinella* spp. larvae is based on isolation of the larvae by artificial digestion of meat samples and microscopic identification (Regulation (EC) No 2075/2005); see also Section 3.4.1. The sensitivity of the current detection methodology is at least one to three larvae per gram, and it is currently considered as adequate to prevent clinical infection in humans.

In a risk-based carcass meat safety assurance system (as outlined for pigs (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011)), if incoming solipeds were categorised into lower and higher risk categories for *Trichinella* spp. based on FCI, including historical testing results related to the farm of origin, different *post-mortem* handling of slaughtered solipeds in respect of *Trichinella* spp. could be applied to those different risk categories. Namely, carcasses from low-risk solipeds could be passed without having to be either *Trichinella* spp. tested or subjected to *Trichinella* spp. inactivation treatments. In contrast, meat from higher risk solipeds could undergo one of two options: either to be examined for *Trichinella* spp. or to be treated by a reliable and validated larvae-inactivating treatment. The actual applicability of the risk-based meat safety assurance system to control *Trichinella* spp. in carcass meat from solipeds is considered below.

5.1.1. At-farm safety assurance

Theoretically, separation of solipeds during the pre-slaughter phase (i.e. on farm) into lower or higher risk categories with respect to *Trichinella* spp. could be based on certain criteria including: (i) the breeding system, i.e. whether they are, or are not, bred in high-containment systems preventing exposure to the parasite; and/or (ii) the results of serological testing of live solipeds for the parasite; and/or (iii) geographical origin i.e. whether they originate from countries/regions where *Trichinella* spp. is present in the domestic and sylvatic cycles.

With respect to the breeding system criterion, solipeds are not reared under high-containment level conditions. Hence, when comparing the *Trichinella* spp. risk categorisation of solipeds with the *Trichinella* spp. risk categorisation of pigs (Table 13), it is considered that the concept of negligible risk (high containment level) used for pigs cannot be applied for solipeds.

With respect to the serological testing results criterion, it is considered that serological diagnosis is not an acceptable method of detecting or monitoring *Trichinella* spp. infection in solipeds, because anti-*Trichinella* spp. immunoglobulin G is not detectable in sera beyond five to six months after the infection, although there may still infective larvae in the muscles, at least for two to six additional months (Murrell et al., 2004; Pozio et al., 2002; Pozio et al., 1997; Soulé et al., 1989). Furthermore, the option of monitoring of *Trichinella* spp. in live solipeds is hampered by the very low prevalence of the parasite in those animals in the EU. In conclusion, serology-based categorisation of solipeds before slaughter into lower or higher risk for *Trichinella* spp. does not seem to be a feasible option at present but could be an option in the future if a serological test becomes available.

With respect to the geographical origin criterion, apart from general concerns over unreliable or a lack of traceability of solipeds (Liciardi et al., 2009), it is currently not possible to trace all movements of solipeds, as discussed in Section 3.2. Because reliable traceability is a prerequisite for the geographical risk categorisation of animals with respect to *Trichinella* spp., such an option is not currently feasible, but could be applicable in the future if traceability could be fully guaranteed. In particular, it should allow information to be obtained on whether the animal has spent its life in a region(s) with negligible *Trichinella* spp. risk in the domestic and sylvatic cycles.

Table 13: Comparison of breeding practices in pigs and solipeds that can prevent or favour *Trichinella* spp. transmission.

Breeding condition	**Pig**	**Systematic control for *Trichinella* spp.**	**Solipeds**	**Systematic control for *Trichinella* spp.**
High containment level	Yes	No	No[a]	–
Indoor without outdoor access	Yes	Yes	No[b]	–
Indoor with outdoor access	Yes	Yes	Yes	Yes
Backyard	Yes	Yes	Yes	Yes
Free-range	Yes	Yes	Yes	Yes

a: Solipeds are not reared under conditions of high containment.
b: Solipeds always have outdoor access.

5.1.2. At-abattoir safety assurance

Alternative approaches to meat safety assurance with respect to muscle larvae of *Trichinella* spp. have been considered for pigs (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011). They are primarily based on meat treatments with the aim of inactivating (devitalising) the larvae. The most reliable larvae inactivation treatments (Gamble et al., 2000; Gamble et al., 2007) recommended in the context of at-abattoir pork carcass safety assurance are based on the application of: (i) an adequate meat heating regime, e.g. 71 °C for at least one minute in the centre; and (ii) an adequate meat freezing regime, e.g. at least –15 °C for three weeks (if meat is cut into pieces up to 15 cm in thickness) or –15 °C for four weeks (if meat pieces are up to 50 cm thickness), but it should be noted that *T. britovii* in pork can survive up to three weeks at –20 °C.

With respect to the use of *Trichinella* spp. inactivation treatments in the soliped abattoir, there may be some additional concerns and/or difficulties caused by the fact that the carcasses are much larger than porcine carcasses. Compared with pigs, this fact may have negative implications, e.g. slower penetration of *Trichinella* spp. inactivation factors (e.g. heat, cold, curing agents) to the centre of much thicker muscles if the carcass is treated whole and/or more difficult tracing of a larger number of pieces of meat obtained from one deboned/cut carcass.

With respect to heat-based *Trichinella* spp. inactivation treatments of soliped meat, it is considered that an adequate meat heating regime, e.g. 71 °C for at least one minute (in the centre), can inactivate the larvae.

Another treatment that could be considered in the context of *Trichinella* spp. inactivation in soliped carcasses/meat is adequate irradiation, e.g. with doses of 0.3 kGy. The ability of food irradiation to reduce food-borne pathogens in foods and the contribution of irradiation to reduce the risks to human health from food-borne pathogens were reviewed in an EFSA opinion (EFSA Panel on Biological Hazards (BIOHAZ), 2011b). Parasites, including *Trichinella* spp., are generally more sensitive to irradiation than vegetative bacteria, and doses below 1 kGy will prevent the most infective stage of parasites from infecting humans. For example, studies done in pork show that a minimum dose of 0.3 kGy will sterilise the most infective stage of the nematode *T. spiralis* (Gibbs et al., 1964), and can provide a substantial margin of safety for human consumption of heavily infected meat (Brake et al.,

1985). Irradiation of fresh meat can cause changes to the colour, odour and taste, and this is seen by some as a major limitation to the use of irradiation of fresh meat. However, such changes can be reduced by modified atmosphere packaging, reducing the temperature (e.g. irradiating in the frozen state) and the addition of antioxidants (Brewer, 2009). Currently, irradiation technologies are primarily developed and used for sealed packaged food, rather than for large and voluminous substrates such as soliped carcasses. Until now, the irradiation of meat has never been systematically used to inactivate *Trichinella* spp. At the EU level, Directive 1999/2/EC regulates the irradiation of food. Until a Community positive list of foodstuffs that may be treated with ionising radiation is established, fresh meat could be irradiated with an overall average radiation dose of 2 kGy, subject to authorisation at MS level.

On the other hand, *Trichinella* spp. inactivation treatments based on salting/curing of meat could be considered as, for example, those specified for pork in legislated regulations in the USA (USDA, 1990), and it is known that lowering the water activity (a_w) in salted/cured meat to below 0.92 may be adequate to kill *Trichinella* spp. larvae (Gajadhar et al., 2009). However, the degree and the dynamics of a_w lowering and, in turn, the effectiveness in terms of *Trichinella* spp. inactivation of salting/curing is a multifactorial issue. It depends not only on the recipes (i.e. concentrations of the salt/curing agents added, size of meat pieces, temperature and time) but also on the uniformity and the consistency of the technological processes used for various intended meat products. Therefore, the salting/curing treatment is technologically more complex than heating or irradiation, hence a system for its monitoring and control is more difficult. Because neither such a treatment nor such a system have been yet fully developed and applied and also because of their inherent complexity and envisaged problems, salting/curing-based treatments are not currently recommended by the International Committee on Trichinellosis (Gamble et al., 2000).

Furthermore, currently available information suggests that freezing treatment strategies applied to pork for *Trichinella* spp. inactivation may not be similarly effective in soliped meat. Kapel et al. (2004) reported that, while in the meat of pigs and wild boar no *Trichinella* species were able to survive at –18 °C for one week, in horse meat *T. spiralis*, *T. britovi* and *T. pseudospiralis* survived at both –5 °C for one, four and eight weeks, respectively. The authors concluded that horse meat most likely contains substances that effectively prevent freezing of *Trichinella* spp. muscle larvae. The infectivity of the larvae recovered in the study was not discussed by the authors. Hill et al. (2007a) also reported the ability of *T. spiralis* larvae to persist for extended periods of time in frozen horse meat. The authors were able to recover live larvae from samples of horse muscles after up to six weeks of storage at –18 °C. However, a steady reduction in the number of live larvae after cold storage was noted, and the infectivity of the larvae in mice decreased substantially after two days at –18 °C.

Regardless of which potentially effective treatments (heat or irradiation based) are considered for application in practice by the soliped abattoir industry, it is likely that whole-carcass treatment would not be practical in routine abattoir operations at present. However, in principle, adequate treatment regimes could be achieved with soliped meat cuts, i.e. after carcass deboning and cutting operations. Should *Trichinella* spp. inactivation treatments of soliped meat cuts be approved and used in practice, ensuring reliable identification and handling of all parts of the animals during conversion of soliped carcasses into meat cuts, as well as throughout the subsequent treatments applied, would have been of utmost importance. This would have been an absolute prerequisite, so that no muscle piece passes the *Trichinella* spp. inactivation process untreated and enters the food chain. If/where the food business operator (i.e. abattoir) were able to prove that those prerequisites are met and use of a treatment were officially approved, it would have to be accompanied by a reliable, validated, documented, verified and regulatory audited system of process monitoring and control in the context of HACCP.

In principle, and in accordance with the currently recognised and accepted approach to food safety assurance in the EU that puts the primary responsibility for meat safety on to the producers and sees the regulators as primarily in advisory and verification/auditing roles, it should be left to the industry to demonstrate whether applications of effective and reliable treatments—and related implementation of effective and reliable monitoring and control systems—are indeed achievable in practice and, if so,

it should be left to the regulators to ensure that there is an appropriate regulatory verification and auditing system.

5.1.3. Alternative *Trichinella* spp. testing regime

An alternative approach of testing only higher risk solipeds is not considered as realistically applicable at present, because of the difficulties with pre-slaughter *Trichinella* spp. risk categorisation of solipeds indicated above. Also, another alternative approach of testing only a percentage of slaughtered solipeds is not considered as applicable, owing to the very low prevalence of *Trichinella* spp. infection in those animals in the EU (EFSA and ECDC, 2012, 2013): 0.001 % in 2010 and 0 % in 2011. Furthermore, the current approach of testing all slaughtered solipeds is supported by the fact that a large number of consumers are exposed to meat from a single soliped carcass, owing its large size/weight, so one invaded soliped carcass may represent a source of *Trichinella* spp. infection for more than 600 people.

As an alternative to testing each slaughtered soliped carcass for *Trichinella* spp., the meat after the carcass boning/cutting operation could be subjected to validated and verified heat- or irradiation-based *Trichinella* spp. inactivation treatments, as long as conditions that allow reliable identification and handling of all parts of the animals during conversion of soliped carcasses into meat cuts, as well as throughout the subsequent treatments, are implemented. As indicated in Section 5.1.2, if/where the food business operator (i.e. abattoir) were able to prove that those prerequisites are met and the use of heat- or irradiation-based treatment were officially approved, it would have to be accompanied by a reliable, validated, documented, verified and regulatory audited system of process monitoring and control in the context of HACCP.

5.2. Recommendations for additional adaptations of soliped meat inspection

5.2.1. Food chain information

As indicated in previous sections, the use of FCI in the current EU soliped meat inspection system for meat safety purposes has been quite limited. In practice, the use of FCI in the current system has been primarily orientated towards records of medical treatments for solipeds, although the actual accuracy of the records may be questionable in some cases. The first reason for the limited use of FCI may be that the FCI-related regulatory requirements stated in the current legislation for solipeds is different and less stringent than for other species, but this makes their implementation more difficult. The second reason may be the fact that the main prerequisite for development and implementation of an effective FCI system - complete and reliable traceability of solipeds - is not fully reliable in the current soliped meat inspection system. The third possible reason is that the pre-slaughter controls for the most relevant soliped meat-borne hazard, *Trichinella* spp., have not been considered as an important part of the current soliped meat inspection system.

Nevertheless, despite these current limitations, an improved FCI could provide a more useful tool for risk management decisions in an improved soliped carcass meat safety assurance system. To achieve this, potential future FCI improvements need to focus on removing/reducing reasons for its current weaknesses mentioned above, including:

- The FCI requirements in the improved soliped meat safety assurance need to be more specifically defined to enable their practical implementation.

- The traceability of solipeds in the improved soliped meat safety assurance has to be more reliable and ensure the following: (i) it should be compulsory that soliped identification records contain reference to the holding where the animal was born; (ii) all movements (including all farms/holdings where kept) of the solipeds from birth to slaughter should be recorded in a central database; (iii) both these aspects should be applied to all solipeds and managed through an electronic system; and (iv) information available in national databases of identification and movement of solipeds needs to be harmonised.

- If/when a full and reliable soliped traceability system as indicated above is implemented in future, the information whether solipeds have or have not spent their life in a region with negligible *Trichinella* spp. risk in the domestic and sylvatic cycles could be used for the purpose of geographical risk categorisation of solipeds with respect to *Trichinella* spp. Such FCI-based *Trichinella* spp. related risk categorisation would enable the risk manager to consider different ways of handling the solipeds *post-mortem*, e.g. whether to test the carcasses for the parasite, or to subject the carcasses to parasite inactivation treatments, or neither.

5.2.2. *Ante-mortem*

No adaptation of current *ante-mortem* inspection methods is recommended.

5.2.3. *Post-mortem*

Under the current *post-mortem* meat inspection of solipeds, a number of organs/tissues are examined by manual handling (palpation and/or incision). As indicated in previous chapters, the majority of gross lesions that can be detected by macroscopic examination are of animal health and/or meat quality relevance, and do not pose a serious threat to public health. In cases of all those conditions, palpation/incisions conducted during *post-mortem* inspection of solipeds with the aim of detecting them actually have no direct benefit in terms of preventing meat-borne human infections. Conversely, because palpation/incision examinations in such cases result in spread of contamination with microbial meat-borne hazards, they may increase the meat-borne microbial risk.

Most published theoretical considerations and experimental studies on the role of manual techniques (palpation, incision) used during *post-mortem* meat inspection in microbial cross-contamination of meat at abattoirs have been focused on pig slaughter (Hamilton et al., 2002; Nesbakken et al., 2003; Pointon et al., 2000). Those examining this issue at ruminant slaughter have been less common (Brichta-Harhay et al., 2012; Jankuloski D., 2009; Samuel et al., 1980). Related considerations of this problem at soliped slaughter are lacking. Overall, it can be assumed that, while related published experimental data with solipeds are lacking, manual handling during *post-mortem* inspection of solipeds (palpation and/or incision of potentially contaminated lymph nodes and organs/muscles including head splitting) increases the likelihood of microbial cross-contamination of the final carcass and organs. Other related comprehensive considerations on pig/ruminant manual *post-mortem* inspection also have come to the same conclusion (EFSA, 2004; EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011).[18] Therefore, omitting those palpation/incisions would reduce either the total number of carcasses contaminated with microbial pathogens or the total number of the pathogens' cells present on the carcasses entering the post-abattoir stages of the soliped meat chain, or both.

Some conditions detectable by palpation/incision during current *post-mortem* inspection of solipeds (e.g. some cases of enteritis, septicaemia, bone lesions) can be caused by or contain meat-borne hazards, hence it could be argued that related palpation/incisions are beneficial for prevention of meat-borne infections, but there are several significant limitations of the benefits, including the fact that those conditions occur rarely in the EU situation and that many of them are normally detected clinically at *ante-mortem* inspection. In addition, the hazards causing those conditions cannot be differentiated from other non-meat-borne hazards causing similar conditions, i.e. cannot be identified macroscopically at *post-mortem* inspection but only in the laboratory. Finally, these hazards are not assessed in this opinion as being of high priority with regard to meat safety.

More generally, the priority ranking performed in this opinion has not identified any microbial meat-borne hazard as being of high priority with respect to soliped carcass meat safety. Therefore, the spread of these bacteria on soliped carcass/meat as a result of cross-contamination caused by routine

[18] See also: http://www.foodbase.org.uk/results.php?f_report_id=798

palpation/incisions cannot be regarded as posing a high degree of concern for public health. However, any cross-contamination, including when mediated by palpation/incision techniques, is considered to have a detrimental effect on microbiological status of soliped carcass meat.

With respect to muscle sampling for *Trichinella* spp. laboratory testing, as mentioned in previous chapters it can be considered that the risk of sampling-mediated microbial cross-contamination is lower than the risk of cross-contamination mediated by other manual meat inspection procedures. To reduce the risk to a minimum, staff need to be properly trained to use a standardised minimum-handling sampling technique with appropriate between-sample sanitation of hands and any tools used.

At present, in the context of this document, it is not possible to determine the ultimate soliped meat safety outcome of the two opposing aspects: the certain (not high) beneficial effect of palpation-/incision-based detection of those conditions potentially containing meat-borne hazards on meat safety versus the certain (not high) detrimental effect on meat safety of the cross-contamination with hazards arising from the same palpation/incisions. It is likely that the answer to this question lies with the risk manager having actual, specific data (i.e. FCI) on both aspects related to each given, specific epidemiological situation and conditions. Nevertheless, as the majority of gross lesions that are currently targeted by palpation/incision are of soliped health and/or meat quality relevance and do not pose a serious threat to public health, omitting routine palpation/incision and use of visual-only inspection would be desirable for 'non-suspect' solipeds. In solipeds considered as 'suspect' (based on FCI and/or *ante-mortem* examination and/or visual detection of relevant conditions), where more detailed examination is necessary, palpation, incision and, in cases in which glanders is suspected, splitting of the head could be performed away from the slaughter line. In the specific case of head splitting, although outside the scope of this opinion, it is noted that this practice may represent a relevant occupational risk.

5.3. Conclusions and recommendations

- In principle, separation of solipeds during the pre-slaughter phase (i.e. on farm) into lower or higher risk categories with respect to *Trichinella* spp. could be based on certain criteria including the breeding system (high vs. non-high containment system), and/or geographical origin (origin from countries/regions where *Trichinella* spp. is present or not in the domestic and sylvatic cycles).

- Indoor farming of solipeds is not an applicable option, and reliable traceability is a prerequisite for the geographical risk categorisation of animals with respect to *Trichinella* spp., therefore such an option could be applicable on the basis of origin only in cases in which the traceability of movements of solipeds is fully guaranteed.

- In a risk-based system, carcasses from low-risk solipeds could be passed without having to be either *Trichinella* spp. tested or subject to *Trichinella* spp. inactivation treatments. In contrast, meat from higher risk solipeds could undergo one of two options: either to be examined for *Trichinella* spp. or to be treated by a reliable and validated larvae-inactivating treatment.

- At present, without a full and reliable soliped traceability system, it is considered that either testing all slaughtered solipeds for *Trichinella* spp. according to Commission Regulation (EC) No 2075/2005 or inactivation meat treatments should be used to maintain the current level of safety.

- Heat- and irradiation-based treatments can be effective for *Trichinella* spp. inactivation in soliped meat, as long as reliable identification and handling of all parts of animals during the conversion of soliped carcasses into meat cuts, as well as throughout the subsequent treatments applied, is efficiently ensured.

- The use of manual techniques (palpation, incision) during current *post-mortem* soliped meat inspection may increase microbial cross-contamination.

- Taking into account the results of the priority ranking performed, the spread of microbial hazards on soliped carcass/meat as a result of cross-contamination caused by routine palpation/incisions cannot be regarded as posing a high degree of concern for public health. However, any cross-contamination, including that mediated by palpation/incision techniques, is considered to have a detrimental effect on the microbiological status of soliped carcass meat.

- The majority of gross lesions that are currently detected in slaughtered solipeds in the EU by palpation/incision do not pose a serious threat to public health, hence omitting routine palpation/incision and the use of visual-only inspection would be desirable for 'non-suspect' solipeds. In solipeds considered as 'suspect' (based on FCI and/or *ante-mortem* examination and/or visual detection of relevant conditions), where more detailed examination is necessary, palpation and incision and, in cases in which glanders is suspected, splitting of the head should be performed away from the slaughter line.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The conclusions and recommendations relate only to biological, food-borne public health hazards in the context of meat inspection; other hazards are addressed in a separate part of this document.

TOR 1. ***Identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e.g. breeding compared to fattening animals).***

- Identification and priority ranking of the main risks for public health that should be addressed by soliped meat inspection was hampered by the lack of animal and carcass surveillance and epidemiological data.

- According to the decision tree developed, and based on the limited data available, the identified soliped meat-borne biological hazards were categorised as follows:

  - *Trichinella* spp. was assessed as a hazard of low priority with regard to soliped meat inspection. However, this low priority level was judged to be derived from the current hazard-specific control measures applied at the EU level, and in particular from the systematic testing of soliped carcasses for the parasite implemented at the slaughterhouse level in the EU according to meat inspection legislative requirements. Therefore, in agreement with the ranking methodology developed, meat inspection-related aspects of *Trichinella* spp. are discussed further in the opinion.

  - *T. gondii* was not classified in terms of priority with regard to soliped meat inspection because of insufficient data.

  - *B. anthracis*, pathogenic VTEC, *Salmonella* spp. (including ESBL/AmpC gene-carrying *Salmonella* spp.) and *Y. enterocolitica* were classified as hazards of low priority with regard to soliped meat inspection. This low priority level was judged not to be derived from the current hazard-specific control measures applied at the EU level.

TOR 2. ***Assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at ante-mortem or post-mortem inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.***

- Strengths:

  - In principle, utilising FCI to better focus *ante-mortem* and/or *post-mortem* meat inspection is beneficial.

  - *Ante-mortem* inspection enables the detection of clinically observable zoonotic diseases, animal identification enabling traceability and visual evaluation of the cleanliness of animals.

  - *Post-mortem* inspection enables the detection of macroscopic lesions associated with some biological hazards causing zoonotic diseases, e.g. glanders and strangles (non-meat-borne), as well as detection of *Trichinella* spp. by laboratory examination.

- *Ante-mortem* and *post-mortem* inspection detect visible faecal contamination of the skin and dressed carcasses, which is relevant for potential cross-contamination of the meat.

- Weaknesses:

  - The current soliped traceability system does not include compulsory recording in databases of all movements of solipeds from birth to slaughter.

  - Currently FCI is used only to a limited extent and does not include sufficient data to classify solipeds in relation to the meat safety risk associated with the handling, preparation and consumption of soliped meat.

  - There is no evidence to suggest that *ante-mortem* visual assessment of the cleanliness of solipeds is routinely applied in practice.

  - Manual handling of meat, including the use of palpation/incision techniques during *post-mortem* inspection aimed at the detection of some non-zoonotic and/or zoonotic but non-meat-borne hazards, mediates cross-contamination. It does not contribute to the detection of relevant hazards, i.e. *Trichinella* spp. Hence, these two opposing effects of palpation/incision have to be considered carefully to ensure an overall benefit for public health. To a lesser extent, such cross-contamination concerns may also be related to manual sampling for *Trichinella* spp. testing.

  - Microbial agents associated with common pathological conditions detected at *post-mortem* inspection of solipeds (e.g. pneumonia, abscesses) are caused by non-zoonotic and/or zoonotic hazards, and the latter generally pose an occupational rather than a food-borne risk.

  - Judgement of the fitness of meat for human consumption in current *post-mortem* inspection does not differentiate food safety aspects (related to the spread of soliped meat-borne hazards through the food chain) from meat quality aspects, prevention of animal diseases and occupational hazards.

TOR 3. ***If new hazards currently not covered by the meat inspection system (e.g. Salmonella, Campylobacter) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.***

- No specific amendments of the current meat inspection methodology are discussed or recommended as any hazard not currently covered by meat inspection were classified as low priority in the answer to TOR 1.

TOR 4. ***Recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria (see Annex 2). When appropriate, food chain information should be taken into account.***

- In principle, separation of solipeds during the pre-slaughter phase (i.e. on farm) into lower or higher risk categories with respect to *Trichinella* spp. could be based on certain criteria including the breeding system (high vs non-high containment system), and/or geographical origin (origin from countries/regions where *Trichinella* spp. is present or not in the domestic and sylvatic cycles).

- Indoor farming of solipeds is not an applicable option, and reliable traceability is a prerequisite for the geographical risk categorisation of animals with respect to *Trichinella* spp., therefore such an option could be applicable on the basis of origin only in cases in which the traceability of movements of solipeds is fully guaranteed.

- In a risk-based system, carcasses from low-risk solipeds could be passed without having to be either *Trichinella* spp. tested or subject to *Trichinella* spp. inactivation treatments. In contrast, meat from higher risk solipeds could undergo one of two options: either to be examined for *Trichinella* spp. or to be treated by a reliable and validated larvae-inactivating treatment.

- At present, without a full and reliable soliped traceability system, it is considered that either testing all slaughtered solipeds for *Trichinella* spp. according to Commission Regulation (EC) No 2075/2005 or inactivation meat treatments should be used to maintain the current level of safety.

- Heat- and irradiation-based treatments can be effective for *Trichinella* spp. inactivation in soliped meat, as long as reliable identification and handling of all parts of animals during the conversion of soliped carcasses into meat cuts, as well as throughout the subsequent treatments applied, is efficiently ensured.

- The use of manual techniques (palpation, incision) during current *post-mortem* soliped meat inspection may increase microbial cross-contamination.

- Taking into account the results of the priority ranking performed, the spread of microbial hazards on soliped carcass/meat as a result of cross-contamination caused by routine palpation/incisions cannot be regarded as posing a high degree of concern for public health. However, any cross-contamination, including that mediated by palpation/incision techniques, is considered to have a detrimental effect on the microbiological status of soliped carcass meat.

- The majority of gross lesions that are currently detected in slaughtered solipeds in the EU by palpation/incision do not pose a serious threat to public health, hence omitting routine palpation/incision and the use of visual-only inspection would be desirable for 'non-suspect' solipeds. In solipeds considered as 'suspect' (based on FCI and/or *ante-mortem* examination and/or visual detection of relevant conditions), where more detailed examination is necessary, palpation and incision and, in cases in which glanders is suspected, splitting of the head should be performed away from the slaughter line.

RECOMMENDATIONS

- Traceability (identification and movements) systems for solipeds intended for slaughter should be improved in order to improve the FCI in relation to their origin and movements throughout their life.

- Because the hazard identification and ranking relates to the EU as a whole, refinements reflecting differences among regions or production systems are recommended if/where hazard monitoring indicates.

- Furthermore, as new hazards might emerge and/or hazards that at present are not a priority might become more relevant over time or in some regions, both hazard identification and the ranking are to be revisited regularly to reflect this dynamic epidemiological situation.

- Insufficient/lack of data and related assessment uncertainties were issues in the priority ranking exercise in this opinion. This was particularly relevant for *T. gondii*, for which it was

impossible to reach a definitive conclusion about the priority ranking. Hence, it is recommended that data on the occurrence of viable *T. gondii* tissue cysts are collected.

- In order to improve future ranking exercises it is imperative that harmonised data are collected on:
  - the incidence and severity of human diseases caused by relevant hazards;
  - source attribution;
  - the identification and ranking of emerging hazards that could be transmitted through handling, preparation and consumption of soliped meat.
- The development and implementation of a harmonised FCI data collection and analysis system for the main hazards in solipeds at both the farm and the abattoir level are recommended.

REFERENCES

AA.VV., 2010. The Merck veterinary manual. Tenth edition. Ed Kahn, CM Publisher Zelko, G., pp. 2945.

Al-Khalidi NW and Dubey JP, 1979. Prevalence of *Toxoplama gondii* infection in horses. Journal of Parasitology, 65, 331-334.

Al-Khalidi NW, Weisbrode SE and Dubey JP, 1980. Pathogenicity of *Toxoplasma gondii* oocysts to ponies. American Journal of Veterinary Research, 41, 1549-1551.

Alagic D, Kozacinski L, Filipovic I, Zdolec N, Hadziosmanovic M, Njari B, Kozacinski Z and Uhitil S, 2008. Microbiological changes during maturation of fermented horse meat sausages. Meso, 10, 200-203.

Alatoom A and Payne D, 2009. An Overview of Arboviruses and Bunyaviruses. Labmedicine, 40, 237-240.

Alton Y, Heydorn AO and Janitschke K, 1977. Zur infektiosität von *Toxoplasma* oozysten für das pferd. Berl Munch Tierarztl Wochensch, 90, 433-435.

Anderson GD and Lee DR, 1976. *Salmonella* in horses - source of contamination of horse-meat in a packing plant under federal inspection. Applied and Environmental Microbiology, 31, 661-663.

Bacci C, Paris A, Poeta A, Diquattro G, Merialdi G and Bonardi S, 2002. Evaluation of microbial components of ground horse meat. Annali della Facolta di Medicina Veterinaria, Universita di Parma, 22, 233-243.

Baril L, Ancelle T, Goulet V, Thulliez P, Tirard-Fleury V and Carme B, 1999. Risk factors for toxoplasma infection in pregnancy: A case-control study in France. Scandinavian Journal of Infectious Diseases, 31, 305-309.

Barrett NJ, 1986. Communicable disease associated with milk and dairy-products in England and Wales - 1983-1984. Journal of Infection, 12, 265-272.

Baverud V, Gustafsson A, Franklin A, Aspan A and Gunnarsson A, 2003. *Clostridium difficile*: prevalence in horses and environment, and antimicrobial susceptibility. Equine Veterinary Journal, 35, 465-471.

Baverud V, Gustafsson A, Franklin A, Lindholm A and Gunnarsson A, 1997. *Clostridium difficile* associated with acute colitis in mature horses treated with antibiotics. Equine Veterinary Journal, 29, 279-284.

Beatty ME, Ashford DA, Griffin PM, Tauxe RV and Sobel J, 2003. Gastrointestinal anthrax - Review of the literature. Archives of Internal Medicine, 163, 2527-2531.

Bender JB and Tsukayama DT, 2004. Horses and the risk of zoonotic infections. Veterinary Clinics of North America-Equine Practice, 20, p. 643.

Boireau P, Vallee I, Roman T, Perret C, Liu MY, Gamble HR and Gajadhar A, 2000. *Trichinella* in horses: a low frequency infection with high human risk. Veterinary Parasitology, 93, 309-320.

Brake RJ, Murrell KD, Ray EE, Thomas JD, Muggenburg BA and Sivinski JS, 1985. Destruction of *Trichinella spiralis* by low-dose irradiation of infected pork. Journal of Food Safety, 7, 127-143.

Brewer MS, 2009. Irradiation effects on meat flavor: a review. Meat Science, 81, 1-14.

Brichta-Harhay DM, Arthur TM, Bosilevac JM, Kalchayanand N, Schmidt JW, Wang R, Shackelford SD, Loneragan GH and Wheeler TL, 2012. Microbiological analysis of bovine lymph nodes for the detection of *Salmonella enterica*. Journal of Food Protection, 75, 854-858.

Burd EM, Juzych LA, Rudrik JT and Habib F, 2007. Pustular dermatitis caused by *Dermatophilus congolensis*. Journal of Clinical Microbiology, 45, 1655-1658.

Catsaras M, 1966. On an epidemic of *Salmonella* Typhimurium food poisoning caused by horsemeat. Annales de l'Institut Pasteur de Lille, 17, 239-241.

CDC (Center for Disease Control and Prevention), 1983. Group C streptococcal infections associated with eating homemade cheese-New Mexico. Morbidity and Mortality Weekly Report, 32, 510-516.

CDC (Center for Disease Control and Prevention), 2000. Human ingestion of *Bacillus anthracis*-contaminated Meat, Minnesota, August 2000. Morbidity and Mortality Weekly Report, 49, 813-816.

Chalmers RM, Thomas DR and Salmon RL, 2005. Borna disease virus and the evidence for human pathogenicity: a systematic review. International Journal of Medicine, 98, 255-274.

Collobert JF, Guyon R, Dieuleveux V and Dorey F, 2001. Contamination of horse carcasses with *Salmonella* spp., *Campylobacter* spp. and *Escherichia coli* type O157. Bulletin de la Societe Veterinaire Pratique de France, 85, 186-191.

Cook AJC, Gilbert RE, Buffolano W, Zufferey J, Petersen E, Jenum PA, Foulon W, Semprini AE, Dunn DT and European Res Network C, 2000. Sources of toxoplasma infection in pregnant women: European multicentre case-control study. British Medical Journal, 321, 142-147.

Cuny C, Kuemmerle J, Stanek C, Willey B, Strommenger B and Witte W, 2006. Emergence of MRSA infections in horses in a veterinary hospital: strain characterisation and comparison with MRSA from humans. Euro Surveillance, 11, 44-47.

de Assis MA, Destro MT, Franco B and Landgraf M, 2000. Incidence of *Listeria* spp. and *Salmonella* spp. in horsemeat for human consumption. International Journal of Food Microbiology, 62, 161-164.

Dorey F and Collobert JF, 1999. Prevalence of *Campylobacter* and *Salmonella* on horse retail meat. Fleischwirtschaft, 79, 89-90.

Dubey JP, 1985. Persistence of encysted *Toxoplasma gondii* in tissues of equids fed oocysts. American Journal of Veterinary Research, 46, 1753-1754.

Dubey JP, 1988. Long-term persistence of *Toxoplasma gondii* in tissues of pigs inoculated with *T. gondii* oocysts and effect of freezing on viability of tissue cysts in pork. American Journal of Veterinary Research, 49, 910-913.

Dubey JP, 1996. Strategies to reduce transmission of *Toxoplasma gondii* to animals and humans. Veterinary Parasitology, 64, 65-70.

Dubey JP, Brake RJ, Murrell KD and Fayer R, 1986. Effect of irradiation on the viability of *Toxoplasma gondii* cysts in tissues of mice and pigs. American Journal of Veterinary Research, 47, 518-522.

Dubey JP and Jones JL, 2008. *Toxoplasma gondii* infection in humans and animals in the United States. International Journal for Parasitology, 38, 1257-1278.

Dubey JP, Lago EG, Gennari SM, Su C and Jones JL, 2012. Toxoplasmosis in humans and animals in Brazil: high prevalence, high burden of disease, and epidemiology. Parasitology, 139, 1375-1424.

ECDC (European Centre for Disease Prevention and Control), 2013. Annual epidemiological report 2012. Report on 2012 surveillance data and 2011 epidemic intelligence data. Stockholm: ECDC; 2013.

EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on Biological hazards on revision of meat inspection for beef raised in integrated production systems. The EFSA Journal 2004, 141, 1-55. doi:10.2903/j.efsa.2004.141

EFSA (European Food Safety Authority), 2005. Opinion of the Scientific Panel on Biological hazards on *Bacillus cereus* and other *Bacillus* spp in foodstuffs. The EFSA Journal 2005, 175, 1-48. doi:10.2903/j.efsa.2005.175

EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Panel on Biological hazards on a request from the European Commission on assessment of the public health significance of meticillin resistant *Staphylococcus aureus* (MRSA) in animals and foods. The EFSA Journal 2009, 993, 1-73.doi:10.2903/j.efsa.2009.993

EFSA (European Food Safety Authority), 2012. Technical hearing on meat inspection of domestic solipeds. Supporting publications 2012:EN-375, 13 pp.

EFSA (European Food Safety Authority), 2013a. Report for 2011 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products. Supporting publications 2013:EN-363, 65 pp.

EFSA (European Food Safety Authority), 2013b. Technical specifications on harmonised epidemiological indicators for biological hazards to be covered by meat inspection of domestic solipeds. EFSA Journal 2013;11(6):3268, 33 pp. doi:10.2903/j.efsa.2013.3268

EFSA and ECDC (European Food Safety Authority and European Centre for Disease Prevention and Control), 2012. The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2010. EFSA Journal 2012;10(3):2597, 442 pp. doi:10.2903/j.efsa.2012.2597

EFSA and ECDC (European Food Safety Authority and European Centre for Disease Prevention and Control), 2013. The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2011. EFSA Journal 2013;11(4):3129, 250 pp. doi:10.2903/j.efsa.2013.3129

EFSA Panel on Biological Hazards (BIOHAZ), 2011a. Scientific Opinion on an update on the present knowledge on the occurrence and control of foodborne viruses. EFSA Journal 2011;9(7):2190, 96 pp.doi:10.2903/j.efsa.2011.2190

EFSA Panel on Biological Hazards (BIOHAZ), 2011b. Scientific Opinion on the efficacy and microbiological safety of irradiation of food. EFSA Journal 2011;9(4):2103, 88 pp. doi:10.2903/j.efsa.2011.2103

EFSA Panel on Biological Hazards (BIOHAZ), 2011c. Scientific Opinion on the public health risks of bacterial strains producing extended-spectrum β-lactamases and/or AmpC β-lactamases in food and food-producing animals. EFSA Journal 2011;9(8):2322, 95 pp. doi:10.2903/j.efsa.2011.2322

EFSA Panel on Biological Hazards (BIOHAZ), 2013. Scientific Opinion on VTEC-seropathotype and scientific criteria regarding pathogenicity assessment. EFSA Journal, 2013;11(4):3138, 106 pp. doi:10.2903/j.efsa.2013.3138

EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011. Scientific Opinion on the public health hazards to be covered by inspection of meat (swine). EFSA Journal 2011;9(10):2351, 198 pp. doi:10.2903/j.efsa.2011.2351

EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2012. Scientific Opinion on the public health hazards to be covered by inspection of meat (poultry). EFSA Journal 2012;10(6):2741, 179 pp. doi:10.2903/j.efsa.2012.2741

Elbez-Rubinstein A, Ajzenberg D, Darde M-L, Cohen R, Dumetre A, Yera H, Gondon E, Janaud J-C and Thulliez P, 2009. Congenital toxoplasmosis and reinfection during pregnancy: case report, strain characterization, experimental model of reinfection, and review. Journal of Infectious Diseases, 199, 280-285.

Espie E, De Valk H, Vaillant V, Quelquejeu N, Le Querrec F and Weill FX, 2005. An outbreak of multidrug-resistant *Salmonella* enterica serotype Newport infections linked to the consumption of imported horse meat in France. Epidemiology and Infection, 133, 373-376.

Ewers C, Grobbel M, Stamm I, Kopp PA, Diehl I, Semmler T, Fruth A, Beutlich J, Guerra B, Wieler LH and Guenther S, 2010. Emergence of human pandemic O25:H4-ST131 CTX-M-15 extended-spectrum-beta-lactamase-producing *Escherichia coli* among companion animals. Journal of Antimicrobial Chemotherapy, 65, 651-660.

Fasanella A, Garofolo G, Galante D, Quaranta V, Palazzo L, Lista F, Adone R and Jones MH, 2010. Severe anthrax outbreaks in Italy in 2004: considerations on factors involved in the spread of infection. New Microbiologica, 33, 83-86.

Fasanella A, Van Ert M, Altamura SA, Garofolo G, Buonavoglia C, Leori G, Huynh L, Zanecki S and Keim P, 2005. Molecular diversity of *Bacillus anthracis* in Italy. Journal of Clinical Microbiology, 43, 3398-3401.

Fouet AS, Smith KL, Keys C, Vaissaire J, Le Doujet C, Levy M, Mock M and Keim P, 2002. Diversity among French *Bacillus anthracis* isolates. Journal of Clinical Microbiology, 40, 4732-4734.

Frye JG and Fedorka-Cray PJ, 2007. Prevalence, distribution and characterisation of ceftiofur resistance in *Salmonella enterica* isolated from animals in the USA from 1999 to 2003. International Journal of Antimicrobial Agents, 30, 134-142.

Gajadhar AA, Pozio E, Gamble HR, Noeckler K, Maddox-Hyttel C, Forbes LB, Vallee I, Rossi P, Marinculic A and Boireau P, 2009. Trichinella diagnostics and control: mandatory and best practices for ensuring food safety. Veterinary Parasitology, 159, 197-205.

Gamble HR, Bessonov AS, Cuperlovic K, Gajadhar AA, van Knapen F, Noeckler K, Schenone H and Zhu X, 2000. International Commission on Trichinellosis: recommendations on methods for the control of *Trichinella* in domestic and wild animals intended for human consumption. Veterinary Parasitology, 93, 393-408.

Gamble HR, Zarlenga DS and Kim CW, 2007. Helminths in meat. In: Food microbiology: fundamentals and frontiers. Eds M.P. Doyle and L.R. Beuchat. ASM Press, Washington, 629-648.

Garcia-Bocanegra I, Cabezon O, Arenas-Montes A, Carbonero A, Dubey JP, Perea A and Almeria S, 2012. Seroprevalence of *Toxoplasma gondii* in equids from Southern Spain. Parasitology International, 61, 421-424.

Gibbs HC, Macqueen KF and Pullin JW, 1964. Further studies of the effects of gamma radiation on pork infected with *Trichinella spiralis*. Can J Public Health, 55, 191-194.

Gibbs P, 2002. Characteristics of spore-forming bacteria. In: Foodborne pathogens: hazards, risk analysis and controls. C. de W. Blackburn P.J. McClure. Woodhead Publishing Ltd, Cambridge, England, 430 pp.

Gibson JS, Cobbold RN and Trott DJ, 2010. Characterization of multidrug-resistant *Escherichia coli* isolated from extraintestinal clinical infections in animals. Journal of Medical Microbiology, 59, 592-598.

Gill CO, 2005. Safety and storage stability of horse meat for human consumption. Meat Science, 71, 506-513.

Giorgi W, 1973. *Salmonella* isolations in the mesenteric lymph nodes of normal slaughtered horses. author's transl. Arquivos do Instituto Biologico, 40, 95-97.

Gregory BC and Waag DM, 2007. Glanders. In: Medical Aspects of Biological Warfare. Eds Office of the Surgeon General and US Army Medical Department Center and School. Department of Defense, Office of The Surgeon General, US Army, Borden Institute, 121-146. Available online: https://ke.army.mil/bordeninstitute/published_volumes/biological_warfare/BW-ch06.pdf

Grinberg A, Learmonth J, Kwan E, Pomroy W, Villalobos NL, Gibson I and Widmer G, 2008. Genetic diversity and zoonotic potential of *Cryptosporidium parvum* causing foal diarrhea. Journal of Clinical Microbiology, 46, 2396-2398.

Hall S, Ryan M and Buxton D, 2001. The epidemiology of *Toxoplasma* infection. In: Toxoplasmosis, a comprehensive clinical guide. Eds Joynson, DHM and Wreghitt, TG. Cambridge Unversity Press, 58-124.

Hamilton DR, Gallas P, Lyall L, Lester S, McOrist S, Hathaway SC and Pointon AM, 2002. Risk-based evaluation of *postmortem* inspection procedures for pigs in Australia. Veterinary Record, 151, 110-116.

Hathcock TL, Schumacher J, Wright JC and Stringfellow J, 1999. The prevalence of *Aeromonas* species in feces of horses with diarrhea. Journal of Veterinary Internal Medicine, 13, 357-360.

Havelaar AH, Haagsma JA, Mangen M-JJ, Kemmeren JM, Verhoef LPB, Vijgen SMC, Wilson M, Friesema IHM, Kortbeek LM, van Duynhoven YTHP and van Pelt W, 2012. Disease burden of foodborne pathogens in the Netherlands, 2009. International Journal of Food Microbiology, 156, 231-238.

Herenda D, Chambers PG, Ettriqui A, Seneviratna P and da Silva TJP, 1994a. Specific diseases of cattle. In: Manual on meat inspection for developing countries. FAO animal production and health paper 119, Rome. Available online: http://www.fao.org/docrep/003/t0756e/T0756E00.htm#TOC

Herenda D, Chambers PG, Ettriqui A, Seneviratna P and da Silva TJP, 1994b. Specific diseases of horses. In: Manual on meat inspection for developing countries. FAO animal production and health paper 119, Rome. Available online: http://www.fao.org/docrep/003/t0756e/T0756E00.htm#TOC

Hill DE, Forbes L, Gajadhar AA and Gamble HR, 2007a. Viability and infectivity of *Trichinella spiralis* muscle larvae in frozen horse tissue. Veterinary Parasitology, 146, 102-106.

Hill DE, Forbes L, Kramer M, Gajadhar A and Gamble HR, 2007b. Larval viability and serological response in horses with long-term *Trichinella spiralis* infection. Veterinary Parasitology, 146, 107-116.

ICMSF (International Commission on Microbiological Specifications for Foods), 1986. Microorganisms in foods 2. Sampling for microbiological analysis. Principles and specific applications. Second edition. ICMSF Blackwell Scientific Publications.

Igbinosa IH, Igumbor EU, Aghdasi F, Tom M and Okoh AI, 2012. Emerging *Aeromonas* species infections and their significance in public health. Scientific World Journal.

Jankuloski D. PM, Angelovski L., Ratkova M., Kostova S., Sekulovski P. (Mak. Vet. Rew.), 2009. Research for role of official veterinary inspector in cross contamination of offal and carcass at slaughterline with use of marker microorganisms. 32 (1), 45-53.

Jones JL and Dubey JP, 2012. Foodborne toxoplasmosis. Clinical Infectious Diseases, 55, 845-851.

Kapel CMO, Webster P, Malakauskas A, Hurnikova Z and Gamble HR, 2004. Freeze tolerance of nine *Trichinella* genotypes in muscle tissue of experimentally infected pigs, horses, wild boars, mice, cats, and foxes. Proceedings of the XIth International Conference on Trichinellosis (ICT-11), August 8-12, 2004, San Diego, California, p.28.

Kapperud G, Jenum PA, StrayPedersen B, Melby KK, Eskild A and Eng J, 1996. Risk factors for *Toxoplasma gondii* infection in pregnancy - results of a prospective case-control study in Norway. American Journal of Epidemiology, 144, 405-412.

Keel MK and Songer JG, 2006. The comparative pathology of *Clostridium difficile*-associated disease. Veterinary Pathology, 43, 225-240.

Kijlstra A and Jongert E, 2008. Control of the risk of human toxoplasmosis transmitted by meat. International Journal for Parasitology, 38, 1359-1370.

Kijlstra A and Jongert E, 2009. *Toxoplasma*-safe meat: close to reality? Trends in Parasitology, 25, 18-22.

Kriem MR, Marrakchi A and Hamama A, 1998. Prevalence of *Listeria* spp. on a variety of meat products in Morocco. Microbiologie, Aliments, Nutrition, 16, 179-187.

Ksiazek TG, Rota PA and Rollin PE, 2011. A review of Nipah and Hendra viruses with an historical aside. Virus Research, 162, 173-183.

Lavilla S, Gonzalez-Lopez JJ, Miro E, Dominguez A, Llagostera M, Bartolome RM, Mirelis B, Navarro F and Prats G, 2008. Dissemination of extended-spectrum beta-lactamase-producing bacteria: the food-borne outbreak lesson. Journal of Antimicrobial Chemotherapy, 61, 1244-1251.

Leadon DP, O'Toole D and Duggan VE, 2012. A demographic survey of unwanted horses in Ireland 2005-2010. Irish Veterinary Journal, 65.

Leverstein-van Hall MA, Dierikx CM, Stuart JC, Voets GM, van den Munckhof MP, van Essen-Zandbergen A, Platteel T, Fluit AC, van de Sande-Bruinsma N, Scharinga J, Bonten MJM, Mevius DJ and Natl ESG, 2011. Dutch patients, retail chicken meat and poultry share the same ESBL genes, plasmids and strains. Clinical Microbiology and Infection, 17, 873-880.

Liciardi M, Marucci G, Addis G, Ludovisi A, Morales MAG, Deiana B, Cabaj W and Pozio E, 2009. *Trichinella britovi* and *Trichinella spiralis* mixed infection in a horse from Poland. Veterinary Parasitology, 161, 345-348.

Linder R, 1997. *Rhodococcus equi* and *Arcanobacterium haemolyticum*: Two "coryneform" bacteria increasingly recognized as agents of human infection. Emerging Infectious Diseases, 3, 145-153.

Lipkin WI, Briese T and Hornig M, 2011. Borna disease virus - fact and fantasy. Virus Research, 162, 162-172.

Lundén A and Uggla A, 1992. Infectivity of *Toxoplasma gondii* in mutton following curing, smoking, freezing or microwave cooking. International Journal of Food Microbiology, 15, 357-363.

Madewell BR, Tang YJ, Jang S, Madigan JE, Hirsh DC, Gumerlock PH and Silva J, 1995. Apparent outbreaks of *Clostridium difficile* associated diarrhea in horses in a veterinary medical teaching hospital. Journal of Veterinary Diagnostic Investigation, 7, 343-346.

Markov K, Frece J, Cvek D, Trontel A, Slavica A and Kovacevic D, 2010. Dominant microflora of fermented horse meat sausages. Meso, 12, 217-221.

Merialdi G, Bardasi L, Fontana MC, Spaggiari B, Maioli G, Conedera G, Vio D, Londero M, Marucci G, Ludovisi A, Pozio E and Capelli G, 2011. First reports of *Trichinella pseudospiralis* in wild boars (*Sus scrofa*) of Italy. Veterinary Parasitology, 178, 370-373.

Messina G, 2007. La macellazione di carni rosse e bianche in Italia nel 2006. Eurocarni, 5, 195-204.

Monteverde JJ, Simeone DH, Morán N, Hermida CA and Colombino MM, 1969. Microbiologia de alimentos VI. Salmonelas en carne y ganglios linfáticos de equinos recién sacrificados. Bacteriologiu de aqua y liquidos residuales. Revista de la facultad de Agronomía y Veterinaria de Buenos Aires, 17, 57-67.

Murrell KD, Djordjevic M, Cuperlovic K, Sofronic L, Savic M, Djordjevic M and Damjanovic S, 2004. Epidemiology of *Trichinella* infection in the horse: the risk from animal product feeding practices. Veterinary Parasitology, 123, 223-233.

Murrell KD and Pozio E, 2011. Worldwide occurrence and impact of human trichinellosis 1986-2009. Emerging Infectious Diseases, 17, 2194-2202.

Nesbakken T, Eckner K, Hoidal HK and Rotterud OJ, 2003. Occurrence of *Yersinia enterocolitica* and *Campylobacter* spp. in slaughter pigs and consequences for meat inspection, slaughtering, and dressing procedures. Int J Food Microbiol, 80, 231-240.

O'Mahony R, Abbott Y, Leonard FC, Markey BK, Quinn PJ, Pollock PJ, Fanning S and Rossney AS, 2005. Methicillin-resistant *Staphylococcus aureus* (MRSA) isolated from animals and veterinary personnel in Ireland. Veterinary Microbiology, 109, 285-296.

Overdevest I, Willemsen I, Rijnsburger M, Eustace A, Xu L, Hawkey P, Heck M, Savelkoul P, Vandenbroucke-Grauls C, van der Zwaluw K, Huijsdens X and Kluytmans J, 2011. Extended-

spectrum beta-lactamase genes of *Escherichia coli* in chicken meat and humans, the Netherlands. Emerging Infectious Diseases, 17, 1216-1222.

PAHO (Pan American Health Organization), 2001a. *Coxiella burnetii*. In: Zoonoses and communicable diseases common to man and animals, Vol. 1. WHO, Washington, D.C.

PAHO (Pan American Health Organization), 2001b. Dermatophytosis. In: Zoonoses and communicable diseases common to man and animals, Vol. 1. WHO, Washington, D.C.

Pavlik I, Jahn P, Dvorska L, Bartos M, Novotny L and Halouzka R, 2004. Mycobacterial infections in horses: a review of the literature. Veterinarni Medicina, 49, 427-440.

Pichner R, Sander A and Gareis M, 2001. Importance of *E.coli* and verotoxin producers (VTEC) in faecal and meat samples from horses. Mitteilungsblatt der Bundesanstalt fuer Fleischforschung, Kulmbach, 40, 109-111.

Pointon AM, Hamilton D, Kolega V and Hathaway S, 2000. Risk assessment of organoleptic postmortem inspection procedures for pigs. Vet Rec, 146, 124-131.

Pollastri D, Magri M, Colantoni A and Fagan S, 1994. Microbiological controls on raw ground equine meat in Parma. Igiene Moderna, 102, 787-798.

Pomares C, Ajzenberg D, Bornard L, Bernardin G, Hasseine L, Darde M-L and Marty P, 2011. Toxoplasmosis and horse meat, France. Emerging Infectious Diseases, 17, 1327-1328.

Pozio E, 2001. New patterns of *Trichinella* infection. Veterinary Parasitology, 98, 133-148.

Pozio E and Murrell KD, 2006. Systematics and epidemiology of *Trichinella*. In: Advances in Parasitology, Vol 63. Eds Baker JR, Muller R, Rollinson D, 367-439.

Pozio E, Sofronic-Milosavljevic L, Morales MAG, Boireau P and Nockler K, 2002. Evaluation of ELISA and western blot analysis using three antigens to detect anti-*Trichinella* IgG in horses. Veterinary Parasitology, 108, 163-178.

Pozio E, Tamburrini A, Sacchi L, Morales MAG, Corona S, Goffredo E and La Rosa G, 1997. Detection of *Trichinella spiralis* in a horse during routine examination in Italy. International Journal for Parasitology, 27, 1613-1621.

Purcell BK, Worsham PL and Friedlander AM, 2007. Anthrax. In: Medical Aspects of Biological Warfare. Eds Office of the Surgeon General and US Army Medical Department Center and School. Department of Defense, Office of The Surgeon General, US Army, Borden Institute, 69-90. Available online: https://ke.army.mil/bordeninstitute/published_volumes/biological_warfare/BW-ch04.pdf.

Quevedo F, Dobosch D and Gonzalez L E, 1973. Contamination of horse meat with *Salmonella*. An ecological study. I. Carrier horses. Gaceta Veterinaria, 35, 119-123.

Radostits OM, Blood DC and C.C. G, 1994. Veterinary medicine: a textbook of the diseases of cattle, sheep, pigs, goats and horses. Bailliere Tindall, London.

Rankin SC, Whichard JM, Joyce K, Stephens L, O'Shea K, Aceto H, Munro DS and Benson CE, 2005. Detection of a bla(SHV) extended-spectrum beta-lactamase in *Salmonella enterica* serovar Newport MDR-AmpC. Journal of Clinical Microbiology, 43, 5792-5793.

Reis Junior JL, Mead D, Rodriguez LL and Brown CC, 2009. Transmission and pathogenesis of vesicular stomatitis viruses. Brazilian Journal of Veterinary Pathology, 2, 49-58.

Saad MD, Hussein HA, Bashandy MM, Kamel HH, Earhart KC, Fryauff DJ, Younan M and Mohamed AH, 2007. Hepatitis E virus infection in work horses in Egypt. Infection Genetics and Evolution, 7, 368-373.

Samuel JL, O'Boyle DA, Mathers WJ and Frost AJ, 1980. The contamination with *Salmonella* of bovine livers in an abattoir. Australian veterinary journal, 56, 526-528.

SCVMRPH (Scientific Committee on Veterinary Measures Relating to Public Health), 2001. Opinion on identification of species/categories of meat-producing animals in integrated production systems where meat inspection may be revised. Available online: http://ec.europa.eu/food/fs/sc/scv/out42_en.pdf.

Soulé C, Dupouycamet J, Georges P, Ancelle T, Gillet JP, Vaissaire J, Delvigne A and Plateau E, 1989. Experimental trichinellosis in horses - biological and parasitological evaluation. Veterinary Parasitology, 31, 19-36.

SVA (National Veterinary Institute), 2010. SVARM 2009, Swedish veterinary antimicrobial resistance monitoring. The National Veterinary Institute (SVA), Uppsala, Sweden, 2010. Available online: http://www.sva.se/upload/Redesign2011/Pdf/Om_SVA/publikationer/Trycksaker/1/Svarm%202009.pdf

SVA (National Veterinary Institute), 2012. SVARM 2011, Swedish veterinary antimicrobial resistance monitoring. The National Veterinary Institute (SVA), Uppsala, Sweden, 2012. Available online: http://www.sva.se/upload/Redesign2011/Pdf/Om_SVA/publikationer/Trycksaker/Svarm2011.pdf

Tassi P, 2007. *Toxoplasma gondii* infection in horses. A review. Parassitologia, 49, 7-15.

Tenter AM, Heckeroth AR and Weiss LM, 2000. *Toxoplasma gondii*: from animals to humans. International Journal for Parasitology, 30, 1217-1258.

Timoney JF, Gillespie JH, Scott FW and Barlough JE, 1988. Hagan and Bruner's microbiology and infectious diseases of domestic animals.

Traub R, Wade S, Read C, Thompson A and Mohammed H, 2005. Molecular characterization of potentially zoonotic isolates of Giardia duodenalis in horses. Veterinary Parasitology, 130, 317-321.

USDA (United States Department of Agriculture), 1990. Code of federal regulations - Animals and animal products, vol. 9. Office of the Federal Register, Government Printing Office, DC, 212–220.

Uyttendaele M, De Troy P and Debevere J, 1999. Incidence of *Listeria monocytogenes* in different types of meat products on the Belgian retail market. International Journal of Food Microbiology, 53, 75-80.

van der Giessen J, Franssen F, Fonvillea M, Kortbeek T, Beckers P, Tolsma P, Stenvers O, Teunis P and Takumi K, 2013. How safe is the meat inspection based on artificial digestion of pooled samples for *Trichinella* in pork? A scenario from wildlife to a human patient in a non-endemic region of Europe. Veterinary Parasitology, In press.

Varcasia A, Garippa G, Pipia AP, Scala A, Brianti E, Giannetto S, Battelli G, Poglayen G and Micagni G, 2008. Cystic echinococcosis in equids in Italy. Parasitology Research, 102, 815-818.

Vengust M, Arroyo LG, Weese JS and Baird JD, 2003. Preliminary evidence for dormant clostridial spores in equine skeletal muscle. Equine Veterinary Journal, 35, 514-516.

Veronesi F, Passamonti F, Caccio S, Diaferia M and Fioretti DP, 2010. Epidemiological survey on equine *Cryptosporidium* and *Giardia* infections in Italy and molecular characterization of isolates. Zoonoses and Public Health, 57, 510-517.

Vo ATT, van Duijkeren E, Fluit AC and Gaastra W, 2007. Characteristics of extended-spectrum cephalosporin-resistant *Escherichia coli* and *Klebsiella pneumoniae* isolates from horses. Veterinary Microbiology, 124, 248-255.

Waldridge BM, Stewart AJ, Taylor DC and Saville WJ, 2011. The incidence of *Aeromonas* species in the feces of nondiarrheic horses. Journal of Equine Veterinary Science, 31, 700-702.

Weese JS, 2002. A review of equine zoonotic diseases: risks in veterinary medicine. Proceedings of the 48th Annual Convention of the American Association of Equine Practitioners, Orlando, Florida, USA, 4-8 December 2002, 362-369.

Weese JS, Archambault M, Willey BM, Dick H, Hearn R, Kreiswirth BN, Said-Salim B, McGeer A, Likhoshvay Y, Prescott JF and Low DE, 2005. Methicillin-resistant *Staphylococcus aureus* in horses and horse personnel, 2000-2002. Emerging Infectious Diseases, 11, 430-435.

Weese JS, Caldwell F, Willey BM, Kreiswirth BN, McGeer A, Rousseau J and Low DE, 2006. An outbreak of methicillin-resistant *Staphylococcus aureus* skin infections resulting from horse to human transmission in a veterinary hospital. Veterinary Microbiology, 114, 160-164.

Weese JS, Staempfli HR and Prescott JF, 2001. A prospective study of the roles of *Clostridium difficile* and enterotoxigenic *Clostridium perfringens* in equine diarrhoea. Equine Veterinary Journal, 33, 403-409.

Whyte R and Wong TL, 2004. *Bacillus cereus*. In: Encyclopaedia of meat sciences, Vol. 2, Eds W.K. Jensen, C. Devine and M. Dikeman. Elsevier, Oxford, 825-830.

Yuen KY, Seto WH, Choi CH, Ng W, Ho SW and Chau PY, 1990. *Streptococcus zooepidemicus* (Lancefield group C) septicemia in Hong-Kong. Journal of Infection, 21, p. 241.

Zaria LT, 1993. *Dermatophilus congolensis* infection (dermatophilosis) in animals and man - an update. Comparative Immunology Microbiology and Infectious Diseases, 16, 179-222.

Zhang W, Shen Q, Mou J, Gong G, Yang Z, Cui L, Zhu J, Ju G and Hua X, 2008. Hepatitis E virus infection among domestic animals in eastern China. Zoonoses and Public Health, 55, 291-298.

Annex A. Additional information on hazards not considered for priority ranking

Bacteria

Actinobacillus equuli and *Actinobacillus lignieresii*

A. lignieresii causes actinobacillosis, a disease characterised by tumorous abscesses of the tongue (i.e. 'wooden tongue') and other forms of granulomatous disease of the head, neck, limbs, and occasionally the lungs, pleura, udder and subcutaneous tissue, primarily in cattle and sheep, but also in horses and pigs. *Actinobacillus equuli* causes a variety of diseases in horses. A few human *A. lignieresii* soft tissue infections originating from contact with, or bites from, cattle or sheep have been reported. *A. equuli* infections may also result from horse or pig bites (Radostits et al., 1994). No food-borne transmission has been documented.

Aeromonas spp.

Aeromonas hydrophila and, more in general, *Aeromonas* spp. have been reported as gastrointestinal pathogens in horses, as well as in other animal species, but are also isolated from faeces of healthy animals (Waldridge et al., 2011). *Aeromonas* spp. have also been described as causing acute gastroenteritis in humans, and can be also found in the faeces of normal animals (Hathcock et al., 1999; Igbinosa et al., 2012). *Aeromonas* spp. are found globally in surface water, drinking water and in a wide range of foods of animal origin (meat and edible organs of sheep and poultry, fish and seafood, raw milk, red meats and pork and beef), and animal faeces appear to be the major source of contamination of foods (Igbinosa et al., 2012). Wound infections and septicaemia have been also described. No specific links, however, have been established between soliped meat and infection in humans.

Bacillus cereus

B. cereus is a soil-associated and ubiquitous organism and can be isolated from plants, ruminant/soliped faeces and raw meat and milk. In respect of meat safety, the main concern linked to *B. cereus* lies with processed meats, owing to the use of seasonings (Whyte and Wong, 2004). *B. cereus* causes two types of food-borne disease: (i) an emetic syndrome, where the toxin is produced in the food; and (ii) a diarrhoeal syndrome, where the toxin is produced in the intestines. For both types of disease, the growth of the pathogen is a prerequisite, as emetic and diarrheal syndromes are associated with ingestion of 10^5–10^8 cells and 10^5–10^7 cells per gram of food, respectively (Gibbs, 2002). The optimum growth temperature is 30–35 °C, although some psychotropic strains, mostly associated with dairy products, can grow at temperatures as low as 5 °C (Gibbs, 2002). The emetic syndrome is primarily associated with rice, potatoes and other starchy foods (most commonly in Japan and Asia), while the diarrheal syndrome is associated with dairy and meat products, soups and sauces (most commonly in Europe and North America) (EFSA, 2005). Risks deriving from soliped meat are therefore related to growth or introduction of the microorganism post-carcass chill.

Brucella abortus

Brucellosis caused by *B. abortus* may occur in solipeds, although they are relatively resistant. Soliped carcasses affected by brucellosis are approved for consumption (after removal of affected parts), as *Brucella* bacteria remain viable for only a short period in the muscles after slaughter. Moreover, no reports were found of human infection due to the consumption of soliped meat. Humans may, however, be infected through skin lesions when handling infected material (Herenda et al., 1994a; Weese, 2002).

Burkholderia (*Pseudomonas*) *mallei*

B. mallei causes glanders in solipeds. Human infection by ingestion of infected meat has not been reported, which may be because this pathogen is quickly inactivated in the stomach (Gregory and Waag, 2007). Milk from glanderous mares has been reported as a possible cause of human infection

(Gregory and Waag, 2007). Moreover, it should be noticed that monogastric animals have died from *B. mallei* infection from ingesting raw meat (Gregory and Waag, 2007).

Burkholderia (Pseudomonas) pseudomallei

Human infections through ingestion of infected meat have not been documented, while humans can be infected by ingesting contaminated milk. Moreover, there have been a few reports of zoonotic transmission, after contamination of skin lesions by exposure to infected animals and tissues, including meat.[19]

Campylobacter spp.

Campylobacteriosis is the most frequently reported zoonosis in Europe with 220 209 confirmed cases in 2011 (EFSA and ECDC, 2013). Poultry and related products are the primary source of human infection. There is no evidence of an epidemiological link between *Campylobacter* cases and the handling, preparation or consumption of soliped meat. This may be a result of the relatively low level of consumption of soliped meat in the EU or the absence of this pathogen in soliped meat products. The limited evidence in the scientific literature supports the latter. In a review of the safety of horse meat for human consumption, Gill (2005) concluded that *Campylobacter* are not commonly found in horse meat. Furthermore, a French study of 320 horse carcasses failed to detect any campylobacters (Collobert et al., 2001). As there are no related species, comparable data were not available and it was concluded that soliped meat consumption was not a risk factor in humans developing campylobacteriosis.

Clostridium botulinum

Clostridial spores are ubiquitous in the environment and are commonly found in the intestines of animals. *C. botulinum* is a Gram-positive, anaerobic, spore-forming bacillus that produces a range of neurotoxins causing severe, sometimes fatal, food-borne illness. It is generally accepted that consumption of products contaminated by *C. botulinum* spores does not cause botulism as germination, multiplication and neurotoxin production must occur before food is consumed. Risks deriving from soliped meat are therefore related to growth or introduction post carcass chill. The one exception to this is infant botulism, associated with the consumption of honey.

Clostridium difficile

C. difficile, traditionally considered to be a hospital-acquired infection, has also been isolated from many domestic and wild animals including horses. Indeed, *C. difficile* is an important cause of colitis in adult horses and foals (Baverud et al., 1997), often following antimicrobial treatment. Various studies have reported a *C. difficile* prevalence of 0–29 % in healthy adult horses (Baverud et al., 2003; Keel and Songer, 2006), rising to 12.7–90 % in horses with diarrhoea (Madewell et al., 1995; Weese et al., 2001). Carcass contamination from contaminated hides and gut contents during slaughter is a possible source of meat contamination as soliped meat may contain low numbers of *C. difficile* spores (Vengust et al., 2003). Although this organism may cause diarrhoea and colitis in humans, evidence of food-borne transmission is limited.

Clostridium perfringens

C. perfringens toxins cause a brief, self-limiting illness associated with high numbers of the organism in foods that have been stored incorrectly, either as a result of slow cooling after cooking or unrefrigerated storage. The risks deriving from soliped meat are related to growth or introduction post carcass chill.

[19] See: http://www.cfsph.iastate.edu/Factsheets/pdfs/melioidosis.pdf

Coxiella burnetii

C. burnetii (*Rickettsia burnetii*) causes Q fever in humans, which is often asymptomatic or in a mild form. For this reason, sporadic cases often go undiagnosed and the true incidence of the disease is unknown. Several epidemic outbreaks have occurred in abattoirs (mostly involving cattle) and wool-processing plants. Other high-risk groups are workers and persons living on farms where cattle, sheep, and goats are raised. The infection has been found in almost all species of domestic animals and many wild animals, including birds. From the public health standpoint, the most important sources of infection for humans are cattle, sheep, and goats (PAHO, 2001a). The main sources of human infection are foetuses, placentas, uteruses, hides and wool, and the main mode of *C. burnetii* transmission to humans is by aerosols (PAHO, 2001a). Although the agent is shed in cow's milk, there are few reported cases of human infection stemming from the consumption of contaminated milk. At present, there are no published reports of Q fever in humans owing to consumption of soliped meat.

Dermatophilus congolensis

D. congolensis causes an epidermitis that can affect cattle, sheep, horses and, less frequently, goats, pigs, cats and dogs. Transmission to humans is generally linked to direct contact with infected animals, and it has been suggested that it may also be spread indirectly by debris from infected animals or ticks (Burd et al., 2007; Zaria, 1993).

ESBL/AmpC gene-carrying *Escherichia coli*

Third-generation cephalosporin resistance in *E. coli* (both strains with the potential to cause human disease and also commensal *E. coli*) is mediated by the production of ESBLs or AmpC β-lactamases. It has been suggested that ESBL/AmpC-producing bacteria are transferred from food animals to humans although there is little or no evidence to support this hypothesis (EFSA Panel on Biological Hazards (BIOHAZ), 2011c; Lavilla et al., 2008; SVA, 2012). Molecular typing studies have established a link between ESBL *E. coli* in food animals (mainly poultry) and humans (Leverstein-van Hall et al., 2011; Overdevest et al., 2011). No evidence is available to indicate transmission of ESBL/AmpC gene-carrying *E. coli* through consumption of soliped meat.

There are also limited animal/carcass prevalence data and most studies report results on clinical samples taken from sport horses. In 2007, a study of 1 347 horse *Enterobacetriaceae* isolates only seven (0.5 %) displayed a resistant phenotype (*E. coli* and *Klebsiella* spp.) (Vo et al., 2007). Of these ESBL genes were detected in five, one carried AmpC β-lactamase genes and six carried integrons. ESBL *E. coli* have also been isolated from horses in Sweden (SVA, 2010), Australia (Gibson et al., 2010) and in various European countries (Ewers et al., 2010). The fact that, under certain conditions, sport horses can be slaughtered for human consumption at the end of their career may pose an increased risk of transmission of this agent though horse meat, but no evidence of this is currently available.

Leptospira spp.

Leptospira spp. cause leptospirosis but have not been identified as soliped meat-related hazards.

Listeria monocytogenes

L. monocytogenes is ubiquitous in the environment and this pathogen has been recovered from 7 % of frozen horse meat samples in Brazil (de Assis et al., 2000) and a similar percentage of Moroccan ground meat samples (Kriem et al., 1998). In an additional study, 6 % of raw cured horse meat was reported to be contaminated with this pathogen (Uyttendaele et al., 1999). The risks deriving from soliped meat are related to growth or introduction post carcass chill.

Mycobacterium bovis, *Mycobacterium tuberculosis* and *Mycobacterium avium* complex

M. bovis and *M. tuberculosis* from the *M. tuberculosis* complex (MTC) have been isolated from horses. Tuberculous lesions in horses may also be caused by the members of the *M. avium* complex

(MAC). Although there is a theoretical risk of infection of the human population, especially for immunocompromised patients, transmission of tuberculosis infection caused by members of MTC and MAC from solipeds to humans has never been documented (Pavlik et al., 2004).

Pasteurella multocida

P. multocida causes a range of disease in animals and humans but has not been identified as a soliped meat-related hazard.

Rhodococcus equi

R. equi is commonly found in the soil and in the faeces of solipeds and other herbivores. This Gram-positive bacterium has long been recognised as a pulmonary pathogen of foals and a cause of other localised infections in foals and occasionally adults. *R. equi* is now considered a pathogen of importance to immunocompromised people, with the majority of human patients suffering from human immunodeficiency virus and lung infections, while in healthy people it is mainly acquired through wound infections (Bender and Tsukayama, 2004; Linder, 1997). Although early human *R. equi* cases (lung infections in immunocompromised, wound infections in healthy people) were largely associated with contact with horses, nowadays infection in humans is derived mostly from environmental exposure through inhalation. The food-borne route has not been documented.

Staphylococcus aureus

Generally *S. aureus* may occur on raw meats, although usually only in low numbers. Although some published data indicate that *S. aureus* can occur in both raw horse meat and processed horse meat products, e.g. salamis (Alagic et al., 2008; Markov et al., 2010), related data for soliped carcasses at abattoir are lacking. Contamination by animal strains of *S. aureus*, which are thought to have a low enterotoxin-forming potential, probably has a lower impact than contamination from human sources (ICMSF, 1986). *S. aureus* competes poorly with the normal microbial flora of raw meat and constitutes a health hazard only when this competing flora is restricted and when products are stored at the incorrect temperature. For enterotoxin production in foods a high number of the pathogenic cells is required. Overall, for *S. aureus* the risk of food-borne disease seems not to be correlated with the presence of the pathogen in raw meat (including meat from solipeds) but rather to improper food handling and storage enabling growth-related toxin production. The risks derived from soliped meat are related to growth or introduction post carcass chill.

Meticillin-resistant *Staphylococcus aureus* (MRSA)

Meat-derived products may also serve as a potential source of MRSA, with CC398 being the MRSA lineage most commonly associated with intensively reared food-producing animals. Strains of MRSA that colonise and infect horses are frequently different from common human strains (Cuny et al., 2006; O'Mahony et al., 2005; Weese et al., 2005). Although it may be possible to quantify the proportion of human disease attributable to these strains in the future, there are only sporadic reports of human disease, usually minor skin infections, attributable to equine MRSA strains (Weese et al., 2006). In general, foods from which MRSA were isolated included raw meat (including pork, beef, lamb, chicken, turkey and on one occasion rabbit), dairy products (milk and cheese) and, in one instance, pancakes. Data on soliped meat are lacking. There is currently no evidence for an increased risk of human colonisation or infection following contact or consumption of food contaminated by CC398 both in the community and in hospital (EFSA, 2009).

Streptococcus equi (including *S. equi* subsp. *zooepidemicus*)

These bacteria cause various diseases in a number of different animal species, including strangles (caused by *S. equi* group C), which is characterised by inflammation of the pharyngeal/nasal mucosa and abscesses of the regional lymph nodes. Group C *streptococci* that are adapted to animals and classified as *S. zooepidemicus* in solipeds lead to various infections, including metritis and abortions in mares and septicaemia in foals (Timoney et al., 1988). In cows, *S. zooepidemicus* can cause acute mastitis when it enters a wound in the teat and *S. zooepidemicus* has been reported as causing rare

sporadic cases of disease and some outbreaks due to consumption of unpasteurised milk and dairy products (Barrett, 1986; CDC, 1983). Although there is a report of the disease caused by *S. zooepidemicus* (in Hong Kong) attributed to the consumption of cooked or raw pork (Yuen et al., 1990), there is no published evidence of the transmission via soliped meat consumption.

Yersinia pseudotuberculosis

Y. pseudotuberculosis is a Gram-negative bacillus widely distributed in Europe, where sporadic human cases, characterised by diarrhoea, abdominal pain and fever, are commonly reported. Although this organism infects a wide range of species including ruminants, pigs, dogs and cats, rodents are the main reservoir of infection, and human infection is usually related to the consumption of contaminated water or vegetables. Although *Y. pseudotuberculosis* infection occurs in solipeds, there is no evidence to suggest that soliped meat is a vehicle of infection in humans. In addition to the results reported in Section 2.2.3.4 on the tests carried out for *Yersinia enterocolitica* in the framework of EU monitoring, one positive finding was reported for *Y. pseudotuberculosis*.

Zoonotic fungi

Dermatophtytes

Dermatophtytes (e.g. *Trichophyton* spp. and *Microsporum* spp.) cause ringworm in solipeds and other animals, which is transmissible to humans via direct contact and cause similar skin infections (PAHO, 2001b). The food-borne transmission route has not been documented.

Parasites

Cryptosporidium spp.

Cryptosporidium parvum and the *Cryptosporidium* horse genotypes have been detected in young foals in North America, Italy and New Zealand (Grinberg et al., 2008; Veronesi et al., 2010). Transmission to humans cannot be directly related to meat consumption but only to the contamination of food, water or fomites with animal faeces infected with these protozoa. Cross-contamination of carcasses due to the accidental breakage of the gut during slaughtering cannot be definitively ruled out; however, solipeds have never been identified as a source of cryptosporidiosis for humans.

Echinococcus spp.

The most important *Echinococcus* species infecting solipeds is *Echinococcus equinus* (genotype G4), which is not zoonotic. There are very few reports on the presence of fertile cysts of *Echinococcus granulosus* (genotype G1), one of the zoonotic species, in solipeds (Varcasia et al., 2008). Human infection originates from environmental contamination, and humans do not directly acquire cystic echinococcosis from solipeds infected with *E. granulosus* cysts. However, the improper discharge of soliped offal can favour the transmission of this parasite to dogs which can spread the parasite eggs in the environment.

Giardia duodenalis

Out of the two zoonotic A and B assemblages of *Giardia duodenalis*, the occurrence of AI and AII genotypes has been documented in horses (Traub et al., 2005). Transmission to humans cannot be directly related to meat consumption but rather to the contamination of food, water or fomites with animal faeces infected with these protozoa. Cross-contamination of animal carcasses due to the accidental breakage of the gut during slaughtering cannot be definitively ruled out; however, solipeds have never been identified as a source of giardiasis for humans.

Viruses

A number of zoonotic viral agents that affect solipeds and can be transmitted to humans are described in the literature. However, transmission pathways include ways other than ingestion by humans of meat from solipeds. Equine zoonotic viral diseases include a number of viruses transmitted through

insect vectors, such as eastern equine encephalitis, western equine encephalitis, Venezuelan equine encephalitis, West Nile fever, Japanese encephalitis, St Louis encephalitis, encephalitis from bunyaviruses, Barmah forest virus infection, Ross River virus infection (Alatoom and Payne, 2009; Weese, 2002).[20] However, Weese (2002) indicates that *post-mortem* examination and handling of infected blood or cerebrospinal fluid may pose a risk to humans for some of these diseases. Transmission of rabies from solipeds to humans is generally linked to transmission through saliva, usually following biting by an infected animal. Pasteurised milk and cooked meat are not expected to pose a risk of infection.[21] In the case of vesicular stomatitis, transmission is generally due to insect vectors and direct contact (contact with vesicular fluid and saliva) (Reis Junior et al., 2009).[22] Very close contact with infected animals is also recognised as a risk factor for the transmission of other viral diseases from horses to humans, such as for Hendra virus and Nipah virus diseases (Ksiazek et al., 2011). Direct contact with saliva, nasal or conjunctival secretions, as well as indirect contact with these, through contaminated food and water, is also thought to be the transmission route to humans of Borna disease virus, but the transmission mode still remains unclear (Chalmers et al., 2005; Lipkin et al., 2011).

Hepatitis E virus (HEV)

Food-borne transmission of HEV from animal products to humans is an emerging concern. Several studies suggest the following food items as risk factors for infection with HEV: pork pies, liver pate, wild boar, undercooked or raw pork, home-made sausages, meat (in general), unpasteurised milk, shellfish and ethnic foods; however, nearly none of these risk factors is sufficiently substantiated (EFSA Panel on Biological Hazards (BIOHAZ), 2011a). Detailed information on HEV cases, including the proportion of food-borne cases, is not available for the EU. Transmission routes other than water and food include transmission by transfusion of infected blood products and maternal–fetal transmission (EFSA Panel on Biological Hazards (BIOHAZ), 2011a). Saad et al. (2007) investigated HEV infection in horses in Egypt, where the virus is endemic in humans, reporting a 13 % seropositivity and detection of the viral genome in 4 % of the samples. They suggested the possible role of horses in the transmission of HEV to humans in Egypt. Zhang et al. (2008) also reported seropositivity to HEV in horses in eastern China. No evidence is available with regard to the role played by soliped meat in the food-borne transmission of HEV.

[20] See: http://www.cfsph.iastate.edu/Factsheets/pdfs/japanese_encephalitis.pdf; http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/VEE_FINAL.pdf
[21] See: http://www.oie.int/fileadmin/Home/eng/Publications_%26_Documentation/docs/pdf/rabies.pdf
[22] See: http://www.cfsph.iastate.edu/Factsheets/pdfs/vesicular_stomatitis.pdf

ABBREVIATIONS

CAC	Codex Alimentarius Commission
DALY(s)	Disability-adjusted life year(s)
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFSA	European Food Safety Authority
ESBL	extended-spectrum β-lactamase
EU	European Union
FCI	food chain information
FVO	Food and Veterinary Office
GHP	good hygiene practice
GFP	good farming practice
GMP	good manufacturing practice
HACCP	Hazard Analysis and Critical Control Point
MDR	Multi-drug resistant
MS(s)	Member State(s)
PCR	polymerase chain reaction
STEC	Shiga toxin-producing *Escherichia coli*, see also VTEC
TESSy	The European Surveillance System
VTEC	verocytotoxin-producing *Escherichia coli*, see also STEC

Appendix B. Assessment on chemical hazards

SUMMARY

Meat inspection in the European Union (EU) is specified in Regulation (EC) No 854/2004. The main objective of meat inspection is to ensure that meat is fit for human consumption. Historically, meat inspection procedures have been designed to control slaughter animals for the absence of infectious diseases, with special emphasis on zoonoses and notifiable diseases. The mandate that meat needs to be fit for human consumption, however, also includes the control of chemical residues and contaminants that could be potentially harmful for consumers. This aspect is not fully addressed by the current procedures.

The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) was asked to identify and rank undesirable or harmful chemical residues and contaminants in domestic solipeds. Such substances may occur as residues in edible tissues from the exposure of the animals to contaminants in feed materials as well as following the possible application of non-authorised substances and the application of authorised veterinary medicinal products and feed additives. A multi-step approach was used for the ranking of these substances into categories of potential concern. As a first step, the CONTAM Panel considered substances listed in Council Directive 96/23/EC and evaluated the outcome of the national residue control plans (NRCPs) for the period 2005–2010. The CONTAM Panel noted that 2.28 % of the total number of results was non-compliant for one or more substances listed in Council Directive 96/23/EC. The available aggregated data indicate the number of samples that were non-compliant with current EU/national legislation. However, in the absence of substance-specific information, such as the tissues used for residue analysis and the actual concentration of a residue or contaminant measured, these data do not allow for a reliable assessment of consumer exposure. Independently from the occurrence data as reported from the NRCPs, other criteria used for the identification and ranking of chemical substances of potential concern included the identification of substances that are found in other testing programmes, that bioaccumulate in the food chain, substances with a toxicological profile of concern, and the likelihood that a substance under consideration will occur in equine carcasses. Taking into account these criteria, the individual compounds were ranked into four categories denoted as being of high, medium, low and negligible potential concern.

Phenylbutazone and cadmium were ranked as being of high potential concern owing to their toxicological properties and because of the occurrence of non-compliant results in NRCP testing.

All other compounds listed in Council Directive 96/23/EC were ranked as being of low or negligible potential concern. Potentially higher exposure of consumers to these substances from horse meat takes place only incidentally, as a result of non-compliance with known and regulated procedures. However, baseline monitoring for the occurrence of substances currently ranked as of low or negligible potential concern in solipeds is desirable.

The CONTAM Panel emphasises that this ranking into specific categories of potential concern is based on current knowledge regarding the toxicological profiles, usage in solipeds, and occurrence as chemical residues and contaminants. Where changes in any of these factors occur, the ranking might need amendment.

The CONTAM Panel was also asked to assess the main strengths and weaknesses of current meat inspection protocols within the context of chemical hazards. It was noted that current procedures for sampling and testing are, in general, well established and coordinated, including follow-up actions subsequent to the identification of non-compliant samples. The system of issuing of a single lifetime identification document (passport) for all solipeds, where it is entirely implemented and properly enforced, should allow for information on traceability, changes of ownership, and follow-up procedures. However, as the single lifetime identification document (passport) system currently is not properly applied/enforced throughout the EU, this may result in animals treated as non-food-producing

animals entering the food chain. Solipeds are commonly regarded as companion/sport/working animals, and thus some animals may receive treatments that are not permitted for food-producing animals. In addition, food chain information (FCI) for domestic solipeds over their entire lifetime may be incomplete or difficult to obtain and this may compromise traceability. Furthermore, a major weakness is that presence of chemical hazards generally cannot be identified by current *ante-/post-mortem* meat inspection procedures at the slaughterhouse level. Moreover, at present, the level of sampling and the substances to be tested for in solipeds is poorly defined across the EU and this is reflected in the variability of sampling intensity between Member States (MSs).

The CONTAM Panel was also asked to identify and recommend inspection methods for new hazards. Such 'new hazards' are organic contaminants that may accumulate in food-producing animals, for which occurrence data in solipeds are scarce and which may not be systematically covered by the NRCPs. Examples are dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs), non dioxin-like PCBs (NDL-PCBs), brominated flame retardants, such as polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), and perfluorinated compounds (PFCs), such as perfluorooctane sulphonate (PFOS) and perfluorooctanoic acid (PFOA). Owing to the nature of their husbandry systems and the age to which solipeds may be kept, they are more likely to have a build-up of persistent environmental contaminants than some other farm animals.

The CONTAM Panel concludes that for solipeds, the FCI should provide information on the specific environmental conditions on the farms where the animals are reared as well as the individual animal history, including treatments. A more robust and reliable identification system is needed to improve traceability for domestic solipeds. The CONTAM Panel recommends that the individual lifetime identification of domestic solipeds and of the 'passport' system (Commission Decision 2000/68/EC, Commission Regulation (EC) No 504/2008) should be strengthened, implemented and enforced throughout the EU. In addition, future monitoring programmes should be based on the risk of occurrence of chemical residues and contaminants, taking into account the completeness and quality of the FCI supplied and the ranking of chemical compounds into categories of potential concern, which ranking needs to be regularly updated. Control programmes for chemical residues and contaminants should be less prescriptive, with sufficient flexibility to adapt to the results of testing and should include 'new hazards'. There is a need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants, particularly for cadmium, which occurs at high prevalence above maximum limits (MLs) in soliped samples. The CONTAM Panel recommends inclusion in the NRCPs for soliped testing for phenylbutazone and also testing for priority 'essential substances', listed in Commission Regulation (EU) No 122/2013, to check compliance with withdrawal periods. In addition, a minimum number of samples, proportional to the production (slaughtered animals) for each MS, should be specified in NRCPs in order to ensure an equal level of control across the EU. Moreover, the development of analytical techniques covering multiple analytes and new biologically based testing approaches should be encouraged and incorporated into the residue control programmes.

TABLE OF CONTENTS

ASSESSMENT OF CURRENT MEAT INSPECTION PROTOCOLS FOR THE IDENTIFICATION OF CHEMICAL SUBSTANCES OF POTENTIAL CONCERN THAT MAY OCCUR AS RESIDUES OR CONTAMINANTS IN SLAUGHTER SOLIPEDS

1. Introduction

Meat inspection in the EU is specified in Regulation (EC) No 854/2004. The main objective of meat inspection is to ensure that meat[1] is fit for human consumption. Historically, meat inspection procedures have been designed to control slaughter animals for the absence of infectious diseases, with special emphasis on zoonoses and notifiable diseases. The mandate that meat needs to be fit for human consumption, however, also includes the control of chemical residues and contaminants in meat that could be potentially harmful for consumers. This aspect is not fully addressed by the current procedures. For the purpose of this document ''chemical residues' 'are defined as the chemical compounds which result from the intentional administration of legal or illegal pharmacologically active substances while ''contaminants' 'are defined as chemical compounds originating unintentionally from the environment.

This document aims to identify undesirable or harmful chemical residues and contaminants that may occur in domestic solipeds taking into account the current legislation and the results from the National Residue Control Plans (NRCPs), implemented in line with Council Directive 96/23/EC.[2] These findings, together with the characteristics of the individual substances and the likelihood that a substance will occur in meat from solipeds, were used to rank chemical residues and contaminants into categories of potential concern. Four categories were established constituting high, medium, low or negligible potential concern. In the second part, the main strengths and weaknesses of current meat inspection protocols were assessed within the context of chemical hazards. The ultimate aim is an overall evaluation of the current strategies for sampling and analytical testing, resulting in recommendations for possible amendments to the current meat inspection protocols.

For the purpose of this document 'domestic solipeds' (also denoted as 'equine animals') refers to animals belonging to the species *Equus caballus* (horses), *Equus asinus* (donkeys) and their cross-breeds (i.e. mules and hinnies).

Note In this opinion, where reference is made to European legislation (Regulations, Directives, Decisions), the reference should be understood as relating to the most current amendment, unless otherwise stated.

1.1. Domestic solipeds

The horse, a subspecies of the wild horse (*Equus ferus*), was domesticated by humans between 4000 and 3000 BC and there are more than 300 different breeds of horse worldwide, used for many different purposes. Historically, horses have been used mainly as working animals (used in transport and agriculture) and as mounted horses for military and police purposes. While these tasks are still fulfilled by horses in many countries worldwide, in Europe horses nowadays are mainly bred as sport and companion animals, while some animals are reared exclusively for food production. Husbandry practices for horses comprise private holdings with very few animals but also large breeding facilities that may contain several hundreds of animals (as either food-producing or non-food-producing animals). Among the large breeding facilities, there are horse farms keeping animals exclusively for milk production. Apart from food (meat, milk), other products such as hide, hair, bone and pharmaceuticals are derived from horses.

[1] The term 'meat' in this opinion is understood to refer to meat and edible tissues (including offal), unless otherwise stated.

[2] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directive 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. OJ L 125, 23.5.96, p. 10–32.

Donkeys have been domesticated from the African wild ass (*E. asinus* subsp. *africanus*), with the term 'ass' being used normally for the wild animals (Singh et al., 2005). Hybrids are called 'mules' (offspring of jacks and mares) and 'hinnies' (offspring of stallions and jenny). Donkeys are distributed worldwide, mostly in semi-arid and mountainous areas, with the highest population being in Asia and Africa (Starkey and Starkey, 2000). In the EU, the donkey population is small but relatively constant, being kept in Northern Europe nowadays for social and/or leisure purposes and in the south and east of the EU mainly for working purposes, and also for the production of meat and milk.

Horses may reach an age of 30 years or more (EFSA, 2012a) and donkeys an age of 40 years (Bliss, 1989; Singh et al., 2005). They may be presented for slaughter at very different ages. Horses bred for meat production are generally slaughtered at a young age, while leisure and sport horses may be submitted for slaughter at a much older age or following injuries or chronic lameness. Animals may be subjected to long-distance transport in mixed groups which may negatively affect the traceability of individual animals and/or the quality of the FCI.

Based on 2010 production data from the NRCPs, around 260 000 horses were slaughtered in the EU, primarily in Italy, Poland, Spain and Romania. Consumption of horse and donkey meat is variable between countries and regions. Horse and donkey meat is consumed in different ways, depending on the geographical area. Fresh meat/minced meat and meat products (e.g. fermented sausages, cured meat) are consumed. Consumer surveys within the EU show that the percentage of people interviewed declaring consumption of horse meat was variable across EU countries, from 0 % to 3 %, and with a variable average daily consumption (see Appendix A from the BIOHAZ Panel).

1.2. Identification of domestic solipeds

Equine animals may be used for multiple purposes including in sports, as companion animals, as working animals and as food-producing animals. In the EU, equine animals are by definition food-producing animals (belonging to the category of ungulates) according to Annex I of Regulation (EC) No 853/2004. Regulation (EC) No 504/2008 (concerning the identification of equine animals)[3] lays down criteria for national bodies issuing identification documents (passports) for individual animals. Under this Regulation, since July 2009, all horses have to be identified by a single lifetime identification document (passport), which is registered under a unique identification (life) number in the database of an officially approved breeding organisation or of an issuing body designated by the competent authority. In addition, the identification system for equine animals shall include a method to ensure an unequivocal link between the identification document and the equine animal (transponder, marks, DNA code).

According to Article 20, point 1 of Regulation (EC) No 504/2008, "*An equine animal shall be deemed to be intended for slaughter for human consumption, unless it is irreversibly declared as not so intended in Part II of Section IX of the identification document*." All horses are born as and remain as food-producing animals until it is indicated in the passport that they are excluded from slaughter for human consumption. An animal designated as a 'non-food-producing animal' must never be sent for slaughter as a food-producing animal. If a passport is lost, the horse will be identified by a 'duplicate' or by a 'replacement' document. Both documents exclude the specific animal from entering into the human food chain (chapter V, Articles 16 and 17, of Commission Regulation (EC) No 504/2008). However, delays in completing passports, the existence of multiple passport issuing bodies and 'loss' or falsification of passports may jeopardise the effectiveness and reliability of the current identification systems and result in animals that have received treatments not approved for food-producing animals being sent for slaughter. Such illicit practices may be used to facilitate the disposal of animals used for sport/companion animal/working animal purposes at the end of their life.

[3] Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae. OJ L 149, 7.6.2008, p. 3–32.

1.3. Veterinary medicinal products (VMPs) used in solipeds

Regulation (EC) No 504/2008, chapter VI, Article 20 details the controls and medication records required for Equidae (solipeds) intended for human consumption. The veterinary medicinal products (VMPs) permitted for use in food-producing equine animals comprise the following:

- those VMPs listed specifically in Table 1 of Regulation (EU) No 37/2010[4] for use in equine animals
- other treatments in accordance with Article 10 of the Directive 2001/82/EC[5] may be applied under the 'cascade' system (i.e. products licensed for other animals and humans, but not specifically for equine animals), to which a withdrawal period of 28 days applies, and
- pharmacologically active substances (denoted as 'essential substances') listed in the Annex to Commission Regulation (EU) No 122/2013,[6] which may be used by derogation on domestic solipeds intended for slaughter for human consumption (subject to a withdrawal period of at least six months).

In the case of equine animals used for sport, as companion animals or as working animals, treatment with VMPs other than those listed above for food-producing animals may be permitted. Any treatment of an equine animal with such VMPs should have the effect of causing the treated animal to be irreversibly declared as not intended for slaughter for human consumption and its identification document (passport) marked accordingly.

In addition to allowing treatment for sport horses with VMPs not allowed for food-producing animals, the Fédération Equestre Internationale (FEI) has anti-doping regulations, including the Equine Prohibited Substances List of the FEI, which are intended to control and channel medication of horses in competition and to prevent and detect cases of doping. The General Regulations (2013) of FEI, Article 143, concern prohibited medications from the doping point of view, and, similarly, horse passports are mentioned in Article 137 but only from the viewpoint of animal identification purposes and not related to the requirement for specific identification of food-producing animals.

The different approach of the EC and the FEI to classification of pharmacologically active substances for treatment of horses may be well demonstrated by the example of the non-steroidal anti-inflammatory drug phenylbutazone, which may have serious adverse effects in susceptible humans (Dodman et al., 2010). As it is not included in Table 1 of the Annex to Regulation (EU) 37/2010 or in the list of 'essential substances' for treatment of Equidae as listed in the Annex to Commission Regulation (EU) No 122/2013, phenylbutazone is not authorised for use in horses intended for human consumption. However, it is listed as a controlled medication by FEI for sport horses and is very widely used for treatment of sport horses.

Owing to the lack of specifically registered drugs, donkeys generally are treated similarly to horses and veterinarians tend to apply the same drug schedules for both species. However, large differences in the kinetics and the excretion profile of a wide array of drugs have been reported between the two species (see Lizarraga et al., 2004 for a review), possibly due to differences in the expression of drug metabolising enzymes. As an example, the oxidation of phenylbutazone to the active metabolite oxyphenylbutazone appears to occur to a much greater extent in donkeys compared to horses (Mealey et al., 1997), with a potential impact on residue accumulation in edible tissues.

[4] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, OJ L 15, 20.1.2010, p. 1–72.

[5] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. OJ L 311, 28.11.2001, p. 1–66.

[6] Commission Regulation (EU) No 122/2013 of 12 February 2013 amending Regulation (EC) No 1950/2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae. OJ L 42, 13.2.2013, p. 1–17.

1.4. Procedures in the current meat inspection of domestic solipeds

Council Regulation (EC) No 854/2004 prescribes that each domestic soliped animal presented for slaughter has to be inspected *ante-* and *post-mortem*. Historically, and still of most importance, inspection in its current form focuses mainly on diseases, and tuberculosis has very much influenced the procedures used. Inspection procedures for domestic solipeds consider the individual animals as inspection units. This is reflected also in the mandatory identification and registration of individual animals via the horse passport system.

1.4.1. Food chain information and *Ante-mortem* inspection

Food Chain Information (FCI) is the animal's life history data from birth, through all stages of rearing, up to the day of slaughter. In particular, the food business operator at the slaughterhouse should receive information related to veterinary medicinal products or other treatments administered to the animal within a relevant period prior to slaughter, together with their administration dates and their withdrawal periods. Moreover, any sampling results taken from the animals within the framework of monitoring and control of residues should also be communicated to the slaughterhouse operators before the arrival of the animals. The identification document (passport) accompanying the animal for slaughter forms part of the FCI and should be checked by the food business operator. After acceptance for slaughter, the official veterinarian should assess the suitability of the animal to enter the food chain (Regulation (EC) No 853/2004, Annex II, Section III, No 8). Domestic solipeds are, in many cases, presented for slaughter as individuals. The extended life of some of these animals, including lengthy periods at different holdings, being kept in different environments, and coming from uses other than specifically as food-producing animals, may preclude reliable and verifiable lifetime FCI (EFSA, 2012a).

Ante-mortem inspection consists of a general clinical investigation. It focuses primarily on clinical signs of disease suggesting systemic infections or other conditions (e.g. traumatic injuries, joint and musculoskeletal inflammations) that might suggest use of VMPs potentially without observing the prescribed withdrawal periods. During the *ante-mortem* health inspection, the official veterinarian shall pay attention to any signs that the animals have had substances with pharmacological effects administered to them or have consumed any other substances which may make their meat harmful to human health. Checking the medication record in the identification document shall therefore be part of this assessment.

1.4.2. *Post-mortem* inspection of domestic solipeds

Based on Regulation (EC) No 854/2004, *post-mortem* inspection was, and still is, directed primarily at the detection of lesions due to infections, based on observation, palpation, and incision.

Visual inspection of the carcass (and offal) may allow, in some cases, for the identification of gross alterations in carcass morphology and organ-specific lesions in lungs, kidneys, liver or other organs that are indicative of recent use of VMPs (with the possibility of non-compliance with withdrawal periods) or acute or chronic exposure to toxic substances. This aspect is not covered in detail in the current meat inspection protocols. However, in most cases exposure to chemical compounds, including substances that accumulate in the body (toxic elements, certain organic pollutants), may not result in typical organ lesions and, therefore, exposure cannot be identified. Hence it needs to be considered that evidence for the presence of chemical residues and contaminants will, in most cases, not be apparent during the current inspection of equine carcasses and organs. Therefore, the meat inspection approach based on 'detect and immediately eliminate', used for biotic (microbiological) hazards in slaughterhouses, is generally not applicable to abiotic hazards.

While monitoring programmes (Council Directive 96/23/EC), which are fully described in Section 1.5, may provide a gross indication of the prevalence of undesirable chemical residues and contaminants in soliped carcasses, the sole intervention possible at abattoir level is the isolation of a suspect carcass as potentially unfit for human consumption, pending results of residue testing.

1.5. Current legislation

Council Directive 96/23/EC prescribes the measures to monitor certain substances and residues thereof in live animals and animal products. It requires that MSs adopt and implement a national residue monitoring plan, referred to as the National Residue Control Plan (NRCP), for defined groups of substances.[7] MSs must assign the task of coordinating the implementation of the controls to a central public body. This public body is responsible for drawing up the national plan, coordinating the activities of the central and regional bodies responsible for monitoring the various residues, collecting the data and sending the results of the surveys undertaken to the Commission each year.

The NRCP should be targeted; samples should be taken on farm and at abattoir level with the aim of detecting illegal treatment or controlling compliance with the maximum residue limits (MRLs) for VMPs according to the Commission Regulation (EU) No 37/2010, with the maximum residue levels (MRLs) for pesticides as set out in Regulation (EC) No 396/2005[8], or with the maximum levels (MLs) for contaminants as laid down in Commission Regulation (EC) No 1881/2006[9]. This means that, in implementing the NRCPs, the MSs target the groups of animals/gender/age combinations where the probability of finding residues is the highest. This approach differs from random sampling, where the objective is to gather statistically representative data, for instance to evaluate consumer exposure to a specific substance.

In contrast to other animal species (i.e. pigs, poultry, cattle, sheep and goats), a minimum number of samples to be taken from solipeds is not set down in Council Directive 96/23/EC nor is there a specific sampling breakdown between Group A (substances having an anabolic effect and unauthorised substances) and Group B substances (veterinary drugs and contaminants). For solipeds, this Directive requires that the number of samples is to be determined by each MS depending on the problems identified. An overview of the sampling frequency carried out the in EU is presented in Table 1. Data have been gathered from the NRCPs for the 2005–2010 period.

It should be noted that sampling intensity varies greatly among MSs, particularly as there is no specified minimum level of sampling. This is reflected in the wide range of sampling proportions applied in the MSs (e.g. in 2010, ranging from 0.0 to 8.8 % of production). Overall, the proportion of sampling across the EU, as presented in Table 1, is of a comparable order of magnitude to that of other food-producing species.

Table 1: Overview of equine sampling intensity in the EU as reported from the National Residue Control Plans for the 2005–2010 period

Year	Equine production (animals)	Number of targeted samples taken	Percentage of equine animals tested[a]
2005	340 317	3 543	0.88
2006	268 099	3 451	1.01
2007	312 969	3 115	1.16
2008	386 302	2 545	0.81
2009	264 538	3 000	0.78
2010	258 362	3 094	1.17

a: Based on the production (slaughtered animals) of the previous year.

In the case of imports from third countries, CHAPTER VI of Directive 96/23/EC describes the system to be followed to ensure an equivalent level of control on such imports. In particular, it specifies (i)

[7] Commission Staff Working Document on the Implementation of National Residue Monitoring Plans in the MSs in 2009 (Council Directive 96/23/EC).

[8] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[9] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. OJ L 364, 20.12.2006, p. 5–24.

that each third country must provide a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I to the Directive, (ii) that such guarantees must have an effect at least equivalent to those provided for in Directive 96/23/EC, (iii) that compliance with the requirements of and adherence to the guarantees offered by the plans submitted by third countries shall be verified by means of the checks referred to in Article 5 of Directive 72/462/EEC[10] and the checks provided for in Directives 90/675/EEC[11] and 91/496/EEC,[12] and (iv) that MSs are required to inform the Commission each year of the results of residue checks carried out on animals and animal products imported from third countries, in accordance with Directives 90/675/EEC and 91/496/EEC.

1.6. Actions taken as a consequence of non-compliant results

In accordance with Article 8 of Directive 96/23/EC, the MSs are requested, as a follow-up, to provide information on actions taken at regional and national level as a consequence of non-compliant results. The Commission sends a questionnaire to the MS to obtain an overview of these actions, for example when residues of non-authorised substances are detected or when MRLs/MLs established in EU legislation are exceeded. The actions taken by the MS may include:

- suspect sampling
- modifications of the NRCP
- other actions taken as a consequence of non-compliant results.

1.6.1. Suspect sampling

Sampling as suspect includes:

- samples taken as a consequence of non-compliant results on targeted samples taken in accordance with the monitoring plan (Article 5 of Directive 96/23/EC);
- samples taken as a consequence of possession or presence of prohibited substances at any point during manufacture, storage, distribution or sale throughout the food and feed production chain (Article 11 of Directive 96/23/EC);
- samples taken where the veterinarian suspects, or has evidence of, illegal treatment or non-compliance with the withdrawal period for an authorised VMP (Article 24 of Directive 96/23/EC).

In summary, this means that the term ‘suspect sample’ applies to a sample taken as a consequence of:

- non-compliant results, and/or
- suspicion of an illegal treatment, and/or
- suspicion of non-compliance with the withdrawal periods.

1.6.2. Modification of the NRCPs

Non-compliant results for a specific substance or group of substances or a specific food commodity should result in intensified controls for this substance/group or food commodity in the plan for the following year.

[10] Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries. OJ L 302, 31.12.1972, p. 28–54.
[11] Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries. OJ L 373, 31.12.1990, p. 1–14.
[12] Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC. OJ L 268, 24.9.1991, p. 56–68.

1.6.3. Other actions

Article 16 and Articles 22–28 of Council Directive 96/23/EC prescribe a series of actions (other than modifications of the residue monitoring plan) to be taken in the case of non-compliant results or infringements to:

- carry out investigations in the farm of origin, such as verification of records and additional sampling;
- hold animals in the farm as a consequence of positive findings;
- slaughter animals in the case of confirmation of illegal treatment and send them to a rendering plant;
- intensify the controls in the farms where non-compliant results were found;
- impound carcasses at the slaughterhouse when non-compliant results have been found;
- declare the carcasses or products of animal origin unfit for human consumption.

It should be noted that targeted sampling as defined by Council Directive 96/23/EC aims at monitoring certain substances and residues thereof in live animals and animal products across EU MSs. In contrast to monitoring, under suspect sampling, a 'suspect' carcass has to be detained at the abattoir until laboratory results confirm or deny conformity with legislative limits for chemical residues. Based on the test results, the carcass can be declared fit or unfit for human consumption. In the first scenario, the carcass is released into the human food chain whereas in the second case the carcass is disposed of.

1.6.4. Self-monitoring residue testing

In addition to the minimum testing requirements which form part of the NRCPs, Council Directive 96/23/EC also establishes the requirements for self-monitoring and co-responsibility on the part of operators.

In accordance with Article 9, chapter III of Council Directive 96/23/EC, MSs shall ensure that the owners or persons in charge of the establishment of initial processing of primary products of animal origin (slaughterhouses) take all necessary measures, in particular by carrying out their own checks, to:

- accept only those animals for which the producer is able to guarantee that withdrawal times have been observed;
- satisfy themselves that the farm animals or products brought into the slaughterhouse do not contain residue levels which exceed maximum permitted limits and that they do not contain any trace of prohibited substances or products.

The farmers and the food processing operators (slaughterhouses) must place on the market only:

- animals to which no unauthorized substances or products have been administered or which have not undergone illegal treatment;
- animals for which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.

2. TOR 1: Identification, classification and ranking of substances of potential concern

2.1. Identification of substances of potential concern

In the current EU legislation, chemical residues and contaminants in live animals and animal products intended for human consumption are addressed in Council Directive 96/23/EC. Identification and ranking of potential concerns within this document include all chemical compounds listed in this

Council Directive. Annex I of Council Directive 96/23/EC groups substances that may be found in animal tissues into two categories:

Group A—Substances having anabolic effects and unauthorised substances

A1. Stilbenes, stilbene derivatives, and their salts and esters

A2. Antithyroid agents

A3. Steroids

A4. Resorcylic acid lactones, including zeranol

A5. Beta-agonists

A6. Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990[13] (repealed by Commission Regulation (EU) No 37/2010)

Group B—Veterinary drugs (including unlicensed substances which could be used for veterinary purposes) and contaminants

B1. Antibacterial substances, including sulphonamides, quinolones

B2. Other veterinary drugs

a) Anthelmintics

b) Anticoccidials

c) Carbamates and pyrethroids

d) Sedatives

e) Non-steroidal anti-inflammatory drugs (NSAIDs)

f) Other pharmacologically active substances

B3. Other substances and environmental contaminants

a) Organochlorine compounds, including polychlorinated biphenyls (PCBs)

b) Organophosphorus compounds

c) Chemical elements

d) Mycotoxins

e) Dyes

f) Others

According to Council Directive 96/23/EC, for solipeds, analysis for chemical residues and contaminants for all of the listed substances is required with the exception of B2f—Other pharmacologically active substances, B3e—Dyes and B3f—Others.

2.2. Classification of chemical substances in the food chain

As one of the objectives of this assessment of current meat inspection protocols is the identification of chemical substances of potential concern that may occur as residues or contaminants in solipeds, but have not been specifically addressed in Council Directive 96/23/EC, a more general grouping of chemical substances was chosen, resulting in the following three major groups:

[13] Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. OJ L 224, 18.8.90, p. 1–8.

- substances that have an anabolic effect and unauthorised substances prohibited for use in food-producing animals, corresponding to Group A substances in Council Directive 96/23/EC;
- VMPs and medicated feed additives, corresponding to Groups B1 and B2 substances in Council Directive 96/23/EC; and
- contaminants, corresponding to Group B3 substances in Council Directive 96/23/EC.

The **first group** of chemicals that may occur in edible tissues as residues are those substances prohibited for use in food-producing animals; these substances correspond largely with Group A substances in Council Directive 96/23/EC. There were different rationales for banning these substances for application to animals and the list of Group A substances comprises compounds that are of toxicological concern (including VMPs for which an acceptable daily intake (ADI) could not be established), as well as substances having anabolic effects and pharmacologically active compounds that may alter meat quality and/or affect animal health and welfare.

A **second group** of chemicals that may be a source of residues in animal-derived foods are VMPs (including antibiotics, anti-parasitic agents and other pharmacologically active substances) and authorised feed additives used in the health care of domestic animals; these substances correspond largely with Group B1 and B2 substances in Council Directive 96/23/EC. These substances have been subjected to assessment and pre-marketing approval by the Committee for Medicinal Products for Veterinary Use (CVMP) of the European Medicines Agency (EMA) according to Regulation (EC) No 470/2009[14] or are licensed as feed additives following a review of the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) according to Regulation (EC) No 1831/2003.[15] For all VMPs and feed additives licensed for use in food-producing animals, an ADI is established on the basis of the pharmacological and toxicological profile of the candidate drug/additive. Compounds for which no toxicological ADI can be established are excluded from approval. On the basis of the established ADI, MRLs are derived for the parent drug or its metabolites/derivatives (marker residues) in target tissues and these MRLs (µg/kg tissue) are used to establish compliance. The list of allowed substances is presented as Annex, Table 1 of Commission Regulation (EU) No 37/2010 and in the Community Register of Feed Additives; it should be noted that for most feed additives listed as allowed for use, no MRL is required.

With regard to antibacterial agents, it is important to state that the ranking of substances of concern in this part of the document considers only toxicological concerns related to the presence of residues. Other aspects, such as the emergence of antimicrobial resistance is considered by the EFSA Panel on Biological Hazards (BIOHAZ Panel) in a separate part of this opinion (see Appendix A of the BIOHAZ Panel).

A **third group** of chemical substances that may occur in edible tissues of equine animals are contaminants that may enter the animal's body via feed, ingested soil, drinking water, inhalation or direct (skin) contact; these substances include the Group B3 substances in Council Directive 96/23/EC. Feed materials for equines consist mainly of roughage and grains, to which individual ingredients can be added. These materials may contain environmental pollutants, as well as natural toxins, including toxic secondary plant metabolites and fungal toxins (mycotoxins). Feed producers have to act in compliance with Commission Directive 2002/32/EC,[16] listing the undesirable substances in feed and feed materials and prescribing maximum contents in feed materials or complete

[14] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council. OJ L 152, 16.6.2009, p. 11–22.

[15] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29–43.

[16] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, p. 10–21.

feedingstuffs. In a recent re-assessment of these undesirable substances in animal feeds, the EFSA Panel on Contaminants in the Food Chain (CONTAM) re-evaluated the risk related to exposure to these substances for animals. Special attention was given to toxic compounds that accumulate or persist in edible tissues, including meat, or are directly excreted into milk and eggs.

2.2.1. Statutory limits

In order to protect public health, Article 2 of Council Regulation (EEC) No 315/93[17] of 8 February 1993 (laying down Community procedures for contaminants in food) stipulates that, where necessary, maximum tolerances for specific contaminants shall be established. Subsequently, a number of MLs for various contaminants in different foodstuffs were laid down in the Annex of Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting MLs for certain contaminants in foodstuffs.

As regards solipeds, MLs were established only for cadmium in horses in this Regulation.

Table 2: Contaminants currently regulated in Regulation (EC) No 1881/2006 in horses

Contaminant	MLs	Health-based guidance values/MOE approach	Assessments: reference
Cadmium	Meat: 0.20 mg/kg wet weight Liver: 0.50 mg/kg wet weight Kidney: 1.0 mg/kg wet weight	TWI: 2.5 µg/kg b.w.	EFSA, 2009a; EFSA CONTAM Panel, 2011a

b.w., body weight; ML, maximum level; MOE, margin of exposure; TWI, tolerable weekly intake.

Further MRLs for certain elements in 'horses, asses, mules or hinnies' are laid down in Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin (originally specified for the use of copper-containing and mercury-containing compounds as pesticides). For copper, the maximum residue levels are 5 mg/kg each for meat and fat and 30 mg/kg each for liver, kidney and edible offal. For mercury compounds (sum of mercury compounds expressed as mercury), the maximum residue levels are 0.01 mg/kg each for meat, fat, liver, kidney and edible offal.

2.3. Ranking of the substances of potential concern

A multi-step approach was used for ranking the potential concern for the three groups of substances that are presented in Sections 2.1 and 2.2. These include:

- evaluation of the outcomes of the NRCPs indicating the number of results that are non-compliant with the current legislation;
- evaluation of the likelihood that specific residues or contaminants, including 'new hazards' (see Section 2.3.5.5), may be present in soliped carcasses;
- consideration of the toxicological profile for chemical substances.

2.3.1. Outcome of the NRCPs within the EU

Data from the NRCPs are published annually and these data were considered as the first step for hazard ranking. Aggregated data for the outcome of the NRCPs for targeted sampling of solipeds from 2005 to 2010 are presented in Tables 3–5. The grouping follows Council Directive 96/23/EC. Data reported in 2005 were from the 25 EU MSs whereas for the subsequent years (2006–2010) data have been gathered from 27 EU MSs, following the accession of Romania and Bulgaria to the EU.

[17] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food. OJ L 37, 13.2.1993, p. 1–3.

Results from suspect sampling are not included, as these results are considered not to be representative of the actual occurrence of chemical residues and contaminants. As stated above, suspect sampling arises as (i) a follow-up to the occurrence of a non-compliant result and/or (ii) on suspicion of illegal treatment at any stage of the food chain and/or (iii) on suspicion of non-compliance with the withdrawal periods for authorised VMPs (Articles 5, 11 and 24 of Council Directive 96/23/EC, respectively).

A non-compliant result refers to an analytical result exceeding the permitted limits or, in the case of prohibited substances, any measured level with sufficient statistical certainty that it can be used for legal purposes.[18] As mentioned above, for VMPs, MRLs are laid down in Commission Regulation (EU) No 37/2010. For pesticides, maximum residue levels are laid down in Regulation (EC) No 396/2005. MLs for contaminants are laid down in Commission Regulation (EC) No 1881/2006. National tolerance levels are sometimes applied by individual MSs for contaminants where no EU maximum levels have been established. For some of the non-allowed veterinary medicinal products, for which no permitted limit can be set, minimum required performance limits (MRPLs) have been established (Commission Decision 2002/657/EC[19]) to make the results of residue monitoring comparable between laboratories and MSs; for residues of some of these substances that are not licensed within the EU for use in food-producing animals, such as chloramphenicol, nitrofurans and their metabolites, and medroxyprogesterone acetate, MRPLs have been established (Commission Decision 2003/181/EC[20]) and are used in the reporting system.

It should be noted that information on the number of total analyses performed for an individual substance is transmitted only by those MS that were reporting at least one non-compliant result for that substance under the NRCPs. Therefore, it is not possible to extract from the data supplied complete information on the individual substances from each subgroup tested or the number of samples tested for an individual substance where no non-compliant result is reported.

In addition, in some cases the same samples were analysed for different substance groups/subgroups and therefore the number of substance groups/subgroups tested is higher than the total number of samples collected. It is to be noted that there is a lack of harmonisation regarding details provided on non-compliant samples for the NRCPs from MSs. This hampers the interpretation and the evaluation of these data. Moreover, no information is readily available on the nature of the positive samples (i.e. whether this refers to muscle, liver, kidney or skin/fat samples) and these results often give no indication of the actual measured concentrations of residues or contaminants. As a result, in the absence of substance-specific information and the actual concentration of a residue or contaminant measured, these data do not allow for assessment of consumer exposure.

[18] As laid down in Article 6 of Decision 2002/657/EC, the result of an analysis shall be considered non-compliant if the decision limit of the confirmatory method for the analyte is exceeded. Decision limit is defined in Article 6(3) as the lowest concentration at which the method can confirm with a defined statistical certainty (99 % for substances for which no permitted limit has been established, and 95 % for all other substances) that the particular analyte is present.

[19] Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results. OJ L 221, 17.8.2002, p. 8–36.

[20] Commission Decision 2003/181/EC of 13 March 2003 amending Decision 2002/657/EC as regards the setting of MRPLs for certain residues in food of animal origin. OJ L 71, 15.3.2003, p. 17–18.

Table 3: Non-compliant (NC) results[(a)] for prohibited substances (Group A) in solipeds reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.[(b)] In brackets: number of Member States providing NC data.

Substance	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
Sub-group	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**
A1 Stilbenes	0	87	0	82	0	73	0	79	0	111	0	81
A2 Thyreostats	0	48	0	48	0	46	0	73	0	69	0	86
A3 Steroids	2	168	3	158	0	139	1	152	0	193	0	160
Epinandrolone	0		0		0		1 (1)		0		0	
17-α Nortestosterone	1 (1)		1 (1)		0		0		0		0	
17-β Nortestosterone	0		1 (1)		0		0		0		0	
Dexamethasone	1 (1)		0		0		0		0		0	
Nandrolone	0		1 (1)		0		0		0		0	
A4 Resorcylic acid lactones (RALs)	0	92	0	89	0	75	2	98	0	95	0	87
α-Zearalanol (zeranol)	0		0		0		1 (1)		0		0	
β-Zearalanol (taleranol)	0		0		0		1 (1)		0		0	
A5 βeta-Agonists	0	165	0	149	0	151	0	149	0	342	0	291
A6 Annex IV compounds	0	186	0	159	0	145	0	169	0	220	1	149
Nitrofurantoin/AHD	0		0		0		0		0		1(1)	

AHD, 1- amino-hydantoin.
(a): One sample can be non-compliant for more than one substance.
(b): Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm

Table 4: Non-compliant (NC) results[(a)] for VMPs (antibacterial substances and other veterinary drugs, Group B1 and B2) in solipeds reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.[(b)] In brackets: number of Member States providing NC data

Substance / Sub-group	2010 (EU-27)		2009 (EU-27)		2008 (EU-27)		2007 (EU-27)		2006 (EU-27)		2005 (EU-25)	
	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
B1 Antibacterials	0	585	2	570	2 (2)	366	1	572	1	585	0	925
Antibacterials (unpecified)	0		0		1 (1)		1 (1)		0		0	
Benzylpenicillin	0		0		1 (1)		0		0		0	
Dihydrostreptomycin	0		1 (1)		0		0		0		0	
Oxytetracycline	0		0		0		0		1 (1)		0	
Sulfadiazine	0		1 (1)		0		0		0		0	
B2a Anthelmintics	1	193	0	242	0	115	0	178	0	214	0	141
Oxfendazole	1 (1)		0		0		0		0		0	
B2b Anticoccidials	1	62	0	41	0	54	0	56	1	54	0	22
Diclazuril	1 (1)		0		0		0		0		0	
Monensin	0		0		0		0		1 (1)		0	
B2c Carbamates and pyrethroids	0	71	0	73	0	55	0	83	0	84	0	62
B2d Sedatives	0	120	0	97	0	89	0	114	0	110	0	96
B2e NSAIDs	10	377	2	332	4	341	4	320	1	375	3	339
Antipyrin-4-methylamino	0		1 (1)		0		0		0		0	
Flunixin	1 (1)		0		0		0		0		0	
Oxyphenylbutazone monohydrate[(c)]	0		0		0		1 (1)		0		0	
Phenylbutazone[(c)]	8 (4)		0		4 (2)		3 (3)		1 (1)		3 (3)	
Salicylic acid	1 (1)		1 (1)		0				0		0	
B2f Other	0	88	0	111	0	83	0	81	0	52	0	43

(a): One sample can be non-compliant for more than one substance.
(b): Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm
(c): Phenylbutazone is licensed in some MSs for use on non-food-producing horses (see section 2.3.5.1.1. for further explanation).

Table 5: Non-compliant (NC) results[(a),(b)] for other substances and environmental contaminants (Group B3) in solipeds reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.[(c)] In brackets: number of Member States providing NC data

Substance Sub-group	2010 (EU-27)		2009 (EU-27)		2008 (EU-27)		2007 (EU-27)		2006 (EU-27)		2005 (EU-25)	
	NC	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**
B3a Organochlorine compounds	4	139	0	135	0	104	0	139	2	121	0	152
PCB 153	0		0		0		0		1 (1)		0	
PCB 180	0		0		0		0		1 (1)		0	
WHO-PCDD/F-PCB-TEQ	2 (1)		0		0		0		0		0	
WHO-PCDD/F-TEQ	2 (1)		0		0		0		0		0	
B3b Organophosphorous compounds	0	91	0	83	0	63	0	86	0	99	0	98
B3c Chemical elements	47	732	34	668	35	665	30	764	109	926	123	973
Cadmium	34 (9)		32 (9)		34 (10)		30 (12)		97 (12)		119 (6)	
Lead	13 (2)		2 (1)		1 (1)		0		11 (5)		4 (2)	
Zinc	0		0		0		0		1 (1)		0	
B3d Mycotoxins	0	57	0	56	0	47	0	77	1	73	0	36
Ochratoxin A	0		0		0		0		1 (1)		0	
B3e Dyes	0	0	0	0	0	0	0	0	0	10	0	0
B3f Other	0	6	0	11	0	7	0	7	0	5	0	7

PCB: polychlorinated biphenyl; PCDD, polychlorinated dibenzo-*p*-dioxin; PCDF, polychlorinated dibenzofurans, TEQ, toxic equivalent.
(a): One sample can be non-compliant for more than one substance.
(b): National tolerance levels are applied by individual MSs for contaminants where no EU MLs have been established.
(c): Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm

A summary of the data presented in the previous tables (Tables 3–5) shows that 434 of the 19 038 samples (2.28 %) analysed in the EU NRCPs during the period 2005–2010 were non-compliant for one or more substance groups listed in Annex I of Council Directive 96/23/EC. Further details are presented in Table 6. As mentioned above, one sample can be non-compliant for multiple substances, so that the number of non-compliant results is higher than the number of non-compliant samples.

Table 6: Analysis of non-compliant (NC) samples[(a)] from solipeds as reported in the National Residue Control Plans[(b)] for the period 2005–2010 in the EU

Period 2005–2010	Group A	Group B1–B2	Group B3	Total
Total samples analysed[(c)]	4 293	8 462	6 283	19 038
Farm level	385	163	118	666
Slaughterhouse level	3 908	8 299	6 165	18 372
Total NC samples	7	34	393	434
Farm level	0	2	0	2
Slaughterhouse level	7	32	393	432

(a): One sample can be non-compliant for more than one substance.
(b): Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm
(c): Some of the samples were analysed for several substances in different subgroups (e.g. same sample analysed for B3a, B3b and B3c); this total represents the total number of samples analysed for at least one substance in the group.

It should be noted that the data in Tables 3–5 provide the results for sampling and testing carried out by MSs under the terms of Council Directive 96/23/EC within the NRCPs. However, there may be other chemical substances of relevance for control in solipeds, particularly in the case of contaminants, which are not included in the NRCPs at all or which are not covered systematically in the NRCPs. Some of these substances are addressed further under TOR 3 of this opinion ('New hazards').

2.3.2. Analysis of the data

The results of the NRCP testing show that 2.28 % of the total samples were non-compliant for one or more substances, with 0.16 %, 0.40 % and 6.25 % being non-compliant for Group A, Group B1/B2 and Group B3 substances, respectively. Of the total number of samples taken for analysis during the period 2005–2010, only 3.5 % were taken at farm level while the remaining 96.5 % were taken at slaughterhouse level. It should be noted that sample details are not always available. Compared with opinions on meat inspection for other species, the low numbers of samples taken at farm level and the low number of non-compliant samples (two) found at farm level precludes an assessment of farm versus slaughterhouse sampling.

The highest proportion of non-compliant samples overall (6.25 %) was for Group B3 substances, contaminants (particularly cadmium and lead),, representing largely exceedances of the MLs/MRLs specified for these substances. For Group A, prohibited substances (0.16 %), and for Group B1/B2 substances, VMPs (0.40 %), the proportions of non-compliant samples were much lower, representing largely illicit use of prohibited substances and exceedances of the MRLs specified for VMPs, respectively.

For prohibited substances (Group A), seven non-compliant results were determined, six samples being found to be non-compliant for anabolic substances (steroids and resorcylic acid lactones) and the other sample being found to be non-compliant for a nitrofuran. While no non-compliant results are reported from the limited farm-level sampling undertaken for solipeds, such sampling is an integral component of the system for controlling illicit use of prohibited substances in food-producing animals, particularly in the case of substances having anabolic effects.

In the case of VMPs (Group B1/B2), most (32 of 34) of the non-compliant results were determined for sampling at slaughterhouse level and the majority of these non-compliant results (71 %) relate to NSAIDs, particularly phenylbutazone. Slaughterhouse-level sampling is appropriate for identifying

non-compliant samples for VMPs, based on compliance with or exceedance of the specified MRLs in edible tissues.

In the case of contaminants (Group B3), all of the non-compliant samples were determined for sampling at slaughterhouse level, and the majority of these non-compliant results (88 %) relate to the chemical element cadmium. Sampling for Group B3 substances is more appropriate, generally, at slaughterhouse level where identification of non-compliant results, based on compliance with or exceedance of specified MRLs/MLs in edible tissues, can be made.

It should be noted too that a direct comparison of data from the NRCPs over the years is not entirely appropriate as the test methods used and the number of samples tested for an individual residue varied between MSs, and the specified MRLs/MLs for some substances may change over time. In addition, there are ongoing improvements in analytical methods, in terms of method sensitivity, accuracy and scope (i.e. the number of substances covered by a method), which affects inter-year and inter-country comparisons. Therefore, the cumulative data from the NRCPs provide only a broad indication of the prevalence and nature of the non-compliant samples.

In conclusion, this compilation of data indicates that residues of the NSAID phenylbutazone and of the contaminant cadmium contribute disproportionately to residues in solipeds, accounting for 1.0 % and 7.3 %, respectively, of non-compliant results in tested samples. In comparison with these two substances, there is a lower prevalence of other abiotic hazards in edible tissues of solipeds and it can be concluded that potentially higher exposure of consumers to these substances from edible tissues of solipeds takes place only incidentally, as a result of mistakes and/or non-compliance with known and regulated procedures.

2.3.3. Criteria for the evaluation of the likelihood of the occurrence of residues or contaminants in solipeds

Independent from the occurrence data, as reported from the NRCPs, substances or groups of chemical substances that may enter the food chain were also evaluated for the likelihood that potentially toxic or undesirable substances might occur in solipeds, including consideration of the various types of solipeds used for meat production.

For prohibited substances and VMPs/feed additives, the following criteria were used:

- the likelihood of the substance(s) being used in an illicit or non-compliant way in solipeds (suitability for solipeds; commercial advantages; treatment of sport horses)
- the potential availability of the substance(s) for illicit or non-compliant usage in solipeds (allowed usage in third countries; availability in suitable form for use in solipeds; non-authorised supply chain availability (‘black market’); common or rare usage as a commercial licensed product)
- the likelihood of the substance(s) occurring as residue(s) in edible tissues of solipeds based on the kinetic data (pharmacokinetic and withdrawal period data; persistence characteristics; special residue issues)
- toxicological profile and nature of hazard and the relative contribution of residues in solipeds to dietary human exposure.

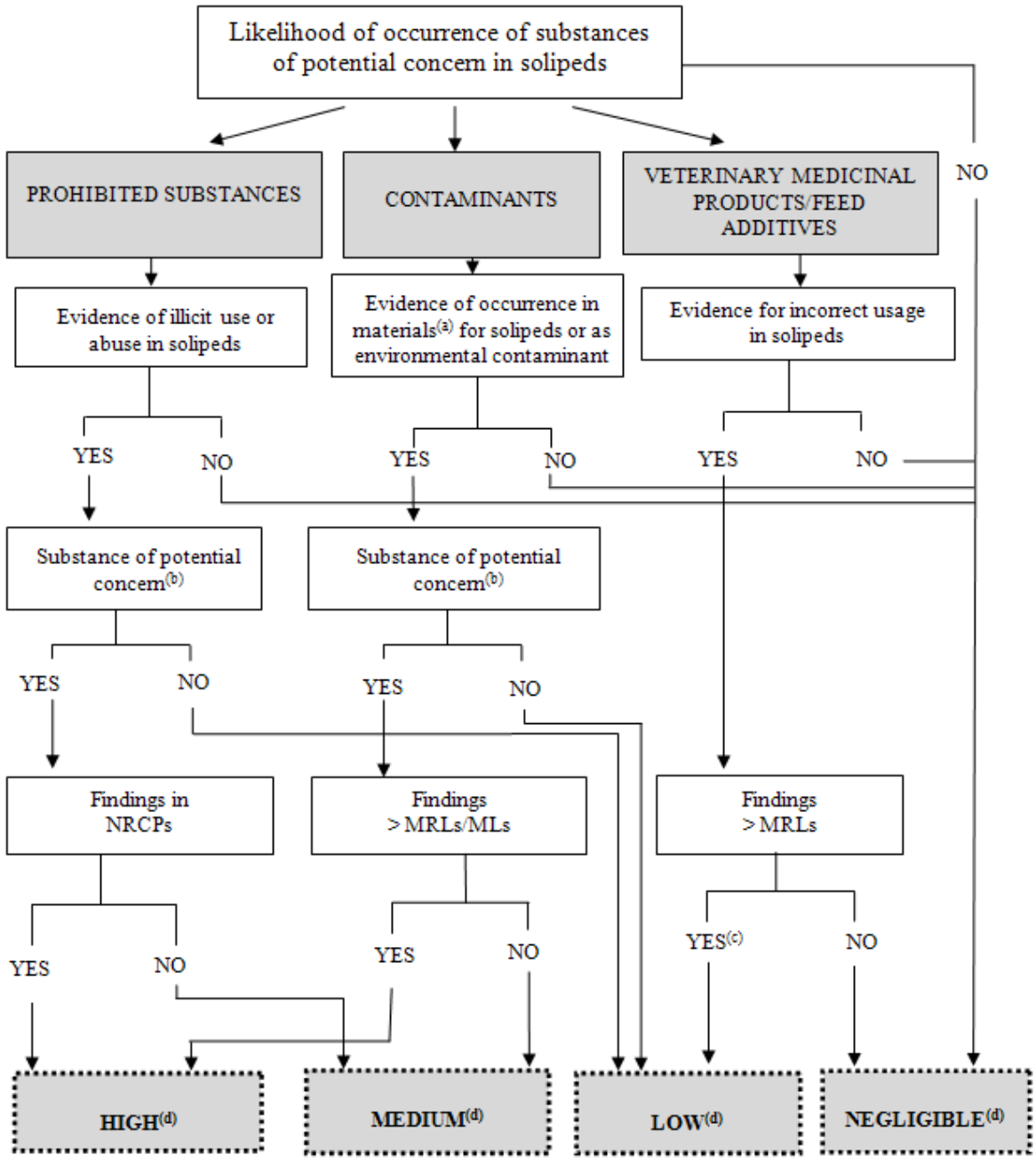
For contaminants, the following criteria were considered:

- the prevalence (where available) of occurrence of the substances in animal feeds/forages and pastures, and in the specific environmental conditions of the farms/holdings
- the level and duration of exposure, tissue distribution and deposition including accumulation in edible tissues of solipeds

- toxicological profile and nature of hazard, and the relative contribution of residues in solipeds to dietary human exposure.

2.3.4. General flow chart

Considering the above mentioned criteria, a flow chart approach was used for ranking of the chemical residues and contaminants of potential concern. The outcome of the NRCPs (indicating the number of non-compliant results), the evaluation of the likelihood that residues of substances of potential concern can occur in solipeds and the toxicological profile of the substances were considered in the development of the general flow chart, as presented in Figure 1.



ML, maximum level; MRL, maximum residue limit; NRCPs, national residue control plans.
(a): Contaminants from the soil and the environment, associated with feed material, are considered to be part of the total feed intake for the purposes of this opinion.
(b): Potential concern was based on the toxicological profile and nature of hazard for the substances.
(c): The CONTAM Panel notes that the ranking of VMPs/feed additives was carried out in the general context of authorised usage of these substances in terms of doses, route of treatment, animal species and withdrawal periods. Therefore, this ranking is made within the framework of the current regulations and control and within the context of a low rate of exceedances in the NRCPs.
(d): See definitions as provided in the next section 2.3.5.

Figure 1: General flow-chart used for the ranking of residues and contaminants of potential concern that can be detected in domestic solipeds.

2.3.5. Outcome of the ranking of residues and contaminants of potential concern that can occur in solipeds

Four categories were established resulting from the application of the general flow-chart:

Category 1—Negligible potential concern

Substance irrelevant for solipeds (no known use at any stage of production); no evidence for illicit use or abuse in solipeds; not or very seldom associated with exceedances in MRLs in control plans; no evidence of occurrence as a contaminant in feed for solipeds.

Category 2—Low potential concern

VMPs/feed additives which have an application for solipeds, residues above MRLs are found in control plans, but substances are of low toxicological concern. contaminants and prohibited substances with a toxicological profile that does not include specific hazards following accidental exposure of consumers, and which are generally not found or are not found above MLs in solipeds.

Category 3—Medium potential concern

Contaminants and prohibited substances to which solipeds are known to be exposed and/or with a history of misuse, with a toxicological profile that does not entirely exclude specific hazards following accidental exposure of consumers; evidence for residues of prohibited substances being found in solipeds; contaminants generally not found in concentrations above the MRLs/MLs in edible tissues of solipeds.

Category 4—High potential concern

Contaminants and prohibited substances to which solipeds are known to be exposed and with a history of misuse, with a distinct toxicological profile comprising a potential concern to consumers; evidence for ongoing occurrence of residues of prohibited substances in solipeds; evidence for ongoing occurrence and exposure of solipeds to feed contaminants.

2.3.5.1. Substances classified in the high potential concern category

2.3.5.1.1. Prohibited substance: phenylbutazone

Phenylbutazone was originally developed for the treatment of rheumatoid arthritis in humans, but was introduced into veterinary medicine already in the 1950s and is predominantly used in equine medicine for the treatment of musculoskeletal disorders. It can be given orally and is metabolised in the liver to a variety of minor metabolites but mainly to oxyphenylbutazone, an active metabolite exerting anti-inflammatory and analgesic effects typical for the class of non-steroidal anti-inflammatory drugs. Various clinical reports state a superior effect of phenylbutazone in certain disease conditions (laminitis) compared with modern NSAIDs, and hence the use of phenylbutazone (often named ‘‘bute’’) continues in equine practice (for review see Soma et al., 2012).

The major concerns regarding the use of phenylbutazone in food-producing animals are based on its properties to induce agranulocytosis and aplastic anaemia in humans (Dodman et al., 2010; EFSA and EMA, 2013). Previous studies also describe comparable effects associated with the main metabolite oxyphenylbutazone, which may induce aplastic anaemia, agranulocytosis, thrombocytopenia, leukopenia, pancytopenia and haemolytic anaemia accompanied with a high mortality rate following therapeutic use in humans (Chaplin, 1986). Moreover, a rare form of sialadenitis (Sweet’s syndrome) has been observed in humans as a consequence of the therapeutic application of phenylbutazone (Levang et al., 2008).

As a result of these toxicological concerns, phenylbutazone is not approved for use in food-producing animals, but is licensed in some MSs for use in sport horses (that are not allowed to enter the food chain). Twenty-four non-compliant results were determined for NSAIDs out of the 2 084 tested samples and 20 of these non-compliant results were positive for phenylbutazone or its metabolite oxyphenylbutazone. The occurrence of phenylbutazone in samples tested under the NRCPs may reflect either misuse of this drug in food-producing horses or the entry of horses, previously designated as non-food producing, into the food chain. These latter animals could represent a possible risk in terms of residues in edible tissues.

The common wisdom of the unique efficacy of phenylbutazone and its easy oral administration, as well as its continuing therapeutic application in sport horses, make its illicit use likely in horses that enter the food chain. This is reflected by the presence of phenylbutazone in samples tested under the NRCPs, despite its relatively short plasma elimination half-life.

Considering the high number of non-compliant results from a number of MSs in most years of the NRCP and its toxicological profile, phenylbutazone is ranked as being of high potential concern.

2.3.5.1.2. Contaminants: heavy metals (cadmium)

Among the chemical elements, heavy metals traditionally have gained attention as contaminants in animal tissues as they may accumulate in certain organs, particularly in the kidneys, over the lifespan of an animal. Exposure of animals is commonly related to contaminated feed materials, despite some reports of accidental intoxication of animals from other sources (paints, batteries). The CONTAM Panel has issued, within the framework of the re-evaluation of undesirable substances in animal feeds according to Council Directive 2002/32/EC, several opinions addressing heavy metals and arsenic in feed materials and the transfer of these elements from feed to edible tissues, milk and eggs. Considering the age of many solipeds presented for slaughter, a relatively high proportion of testing under the NRCP is directed to heavy metals; 25 % of all samples taken for testing, and 75 % of samples taken for testing for contaminants (Group B3), were tested for heavy metals in the NRCPs 2005–2010.

Cadmium

Cadmium (EFSA, 2009a) is a heavy metal found as an environmental contaminant, both through natural occurrence and from industrial and agricultural sources. Cadmium accumulates in humans and animals, causing concentration-dependent renal tubular damage. Following oral ingestion and absorption, which varies in relation to the feed concentration of other bivalent ions, cadmium forms a complex with metallothionein (MT) in the liver. Upon saturation of the MT reserve, unbound cadmium can accumulate in the liver causing liver damage by binding to diverse macromolecules (Klaassen et al., 1999; Nordberg, 2004). The cadmium–MT complex is subsequently transported to the kidney where the cadmium ion complex is cleaved again by lysosomal enzymes, resulting in the accumulation and toxicity of cadmium, particularly in the renal cortex. In horses, renal concentrations of cadmium are much higher (15-fold) than those in the liver (Koizumi et al., 1989). Circulating cadmium binds to different macromolecules resulting in elevated concentrations in muscle tissue. The total body burden increases with the age of horses due to the long half-life of cadmium.

As horses may be slaughtered at high age and older animals are expected to have higher concentrations of cadmium accumulated in the edible tissues, non-compliant results have been found for kidney, liver and muscle tissues. Regulation (EC) No 854/2004 establishes that meat is to be declared unfit for human consumption if it consists of the liver and kidneys of animals more than two years old from regions where implementation of plans approved in accordance with Article 5 of Council Directive 96/23/EC has revealed the generalised presence of heavy metals in the environment.

The results from the NRCPs for the 2005–2010 period show that non-compliant samples for cadmium contribute significantly to the overall percentage of non-compliant samples. Of the 4 728 soliped samples tested for chemical elements, 346 were non-compliant results for cadmium. Non-compliant

results were reported for every year by several MSs. Since horse meat in some regions of the EU is a traditional food, for high consumers of horse meat it is expected to contribute substantially to overall cadmium exposure (EFSA, 2012b).

Considering the high number of non-compliant results from different MSs in all years of the NRCPs, its substantial contribution to the overall exposure for high consumers of horse meat, and its toxicological and kinetic profile, cadmium is ranked as being of high potential concern.

2.3.5.2. Substances classified in the medium potential concern category

No substances were classified in the medium potential concern category for solipeds.

2.3.5.3. Substances classified in the low potential concern category

2.3.5.3.1. Prohibited substances: steroids, resorcylic acid lactones, beta-agonists, chloramphenicol, nitrofurans, chlorpromazine, nitroimidazoles and colchicine

It needs to be emphasised that the extent of testing carried out by the MSs for particular prohibited substances in soliped samples is likely to be variable and, consequently, over-reliance should not be placed on the results of testing.

(a) Steroids

(a.1) Gonadal steroids

A broad range of steroids derived from oestrogens, androgens and progestagens are available and have been used as growth-promoting agents in food-producing animals. There is an extensive body of animal production research demonstrating the efficacy of anabolic steroids, often in combination treatments of an oestrogen and an androgen (or progestagen), as growth promoters. Gonadal steroids are given to animals typically as injections or implants. While all use of steroids as growth-promoting agents in food-producing animals is prohibited (Council Directive 96/22/EC[43]), certain uses of 17β-oestradiol, progesterone and altrenogest in solipeds are allowed for therapeutic or zootechnical purposes only.

Anabolic steroids are widely available on the black-market so there is the possibility for illicit use in solipeds. The results from the European NRCPs 2005–2010 show soliped samples non-compliant for anabolic steroids, particularly alpha- and beta-nortestosterone, and (epi)nandrolone. There are divergent views on the potential adverse effects for the consumer from residues of anabolic steroids in edible tissues of treated animals.

Notwithstanding the toxicological profile of gonadal (sex) steroids, due to the low prevalence of non-compliant samples from confirmed illicit use in the NRCPs, these substances are ranked as of low potential concern.

(a.2) Corticosteroids

Corticosteroids are steroid hormones produced by the adrenal cortex which, as both human and animal remedies, are used for a range of therapies. Only one of the corticosteroids, dexamethasone is approved for use as a VMP in solipeds and, therefore, has associated withdrawal periods and MRLs. In addition to their therapeutic uses, corticosteroids, when used at low dosages, are reported to increase appetite, weight gain and feed efficiency, as well as skeletal muscle mass and carcass characteristics (Courtheyn et al., 2002; Tarantola et al., 2004; Carraro et al., 2009). Testing of samples for corticosteroids was undertaken by most MSs under group B2f—Other pharmacologically active substances, but a number of countries tested for corticosteroids under group A3—Steroids as this

[43] Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC. OJ L 125, 23.5.1996, p. 3–9.

provides them with more legal powers against their illicit use as growth promoters. Only one non-compliant result was recorded overall during the six-year period of NRCP testing 2005–2010.

Considering that, while corticosteroids may be effective for growth promotion in solipeds, the results for the NRCP 2005–2010 do not indicate that there is widespread use of these substances as illicit growth promoters. Therefore, corticosteroids currently are ranked as being of low potential concern. However, it should be noted that illicit use of steroids for doping purposes in sport horses could result in residues of such substances entering the food chain.

(b) Resorcylic acid lactones (RALs)

Zeranol (α-zearalanol) is a non-steroidal anabolic agent with oestrogenic effects and has been used widely as a growth promoter implant in cattle in many countries. Zeranol has been patented in the USA for use as a modulator of the reproductive cycle in female animals, specifically in horses and pigs. Zeranol is derived from and can also occur as a metabolite of the mycotoxin zearalenone, which is produced by *Fusarium* spp.

The results from the European NRCPs 2005–2010 show two non-compliant results for zeranol, and/or its metabolite taleranol, in soliped samples, in one MS in 2007. However, research has shown that the source of the, generally, low levels of zeranol and its metabolites determined in samples may be from exposure of animals to mycotoxins in the diet; the MS stated that the results were '*probably attributable to mycotoxin contamination of feed*'.

Considering that the adverse health effects of zeranol for humans at the residue levels determined in edible tissues is likely to be low, and that the non-compliant results that have been found in NRCP testing are considered to be, in many cases, due to feed contamination with *Fusarium* mycotoxins, zeranol and its metabolites currently are ranked as being of low potential concern.

(c) Beta-agonists

All beta-agonists (such as clenbuterol, salbutamol, cimaterol, terbutaline, ractopamine, etc) are prohibited for use as growth-promoting agents in food-producing animals in the EU. Two beta-agonists, ractopamine and zilpaterol, have been approved for use as growth-promoting agents in some food-producing animals in a number of third countries. One of the beta-agonists, clenbuterol, is licensed for therapeutic use in cattle (as a tocolytic agent) and in the treatment of obstructive airway conditions in horses, and MRLs have been set by Commission Regulation (EU) No 37/2010 related to these therapeutic applications. The results from the European NRCPs 2005–2010 show no non-compliant results for beta-agonists in solipeds. However, a recent (2012) notification from an EU MS under the Rapid Alert System for Food and Feed (RASFF) indicated that residues of clenbuterol above the EU MRL were discovered in horsemeat samples from a Third Country.

As the prolonged administration of therapeutic dosages of beta-agonists may elicit a growth-promoting effect in the horse (Kearns et al., 2001), there is a risk that beta-agonists may be used illegally in sport horses. For example, traces of ractopamine have been recorded from the urine of a race horse in a third country (cited in Wagner et al., 2008).

Considering that beta-agonists, particularly clenbuterol, have known adverse biological effects in humans, but that no non-compliant results were found in NRCP testing, these substances currently are ranked as being of low potential concern.

(d) Chloramphenicol

Chloramphenicol has been widely used as an antimicrobial agent in human and veterinary medicine since the 1950s. However, its use was restricted when it became evident that chloramphenicol may produce idiosyncratic blood dyscrasias in humans, particularly bone marrow aplasia, or aplastic anaemia, which may be fatal. There is no clear correlation between dose and development of aplastic anaemia and the mechanism of induction of aplastic anaemia is not fully understood (Watson, 2004).

Although the incidence of aplastic anaemia associated with exposure to chloramphenicol is apparently very low, no threshold level for the induction of this idiosyncratic aplastic anaemia could be defined (EMEA, 2009). In addition, several studies suggest that chloramphenicol and some of its metabolites are genotoxic (FAO/WHO, 1988, 2004; EMEA, 2009). Considering the available evidence from *in vitro* experiments and from animal studies as well as from a case–control study conducted in China, in which there was evidence for the induction of leukaemia in patients receiving a long-term treatment with chloramphenicol, the International Agency for Research in Cancer (IARC) classified chloramphenicol as a Group 2A (probably carcinogenic to humans) substance (IARC, 1990). Based on these evaluations, the use of chloramphenicol in food-producing animals is prohibited within the EU to avoid the exposure of consumers to potential residues in animal tissues, milk and eggs. Consequently, chloramphenicol is included in Table 2 of Commission Regulation (EU) No 37/2010 (previously Annex IV of Council Regulation (EEC) No 2377/90).

Until its prohibition, chloramphenicol was used in food-producing animals, including horses, for treatment of *Salmonella* infections and for prevention of secondary bacterial infections. Currently, chloramphenicol, which is licensed for use as a broad-spectrum bacteriostatic antibacterial in pets and non-food-producing animals in the EU, is used also in some third countries for food-producing animals. The availability for use in food-producing animals of related substances with similar antibacterial properties, thiamphenicol and florfenicol (with no toxicological concern), should mitigate against the illicit use of chloramphenicol as these alternative drugs are available as prescription medicines. No non-compliant results for chloramphenicol in solipeds have been reported in the results from the NRCPs 2005–2010.

Considering that chloramphenicol has proven toxicity for humans, is effective as an antibacterial treatment for solipeds but that no non-compliant results have been reported from NRCP testing, chloramphenicol currently is ranked as being of low potential concern.

(e) Nitrofurans

Nitrofurans, including furazolidone, furaltadone, nitrofurantoin and nitrofurazone, are very effective antimicrobial agents that, prior to their prohibition for use on food-producing animals in the EU in 1995, were widely used on livestock (cattle, pigs, and poultry), aquaculture and bees. Various nitrofuran antimicrobials are still applied in human medicine particularly for the treatment of urinary tract infections. A characteristic of nitrofurans is a short half-life of the parent compounds and the formation of covalently-bound metabolites which, under the acidic conditions of the human stomach, may be released as active agents (Hoogenboom et al., 1992). The tissue-bound metabolites of nitrofurans have been shown to be potentially carcinogenic and mutagenic; for example, the metabolite of furazolidone, 3-amino-oxazolidone-2 (AOZ), that can be released from covalently bound residues in tissues has been shown to be mutagenic and may be involved in the carcinogenic properties of the parent compound (EMEA, 1997a). These covalently-bound metabolites are used as marker residues for detecting the illicit use of nitrofurans in animal production. It should be noted that the metabolite semicarbazide (SEM) has been shown not to be an unambiguous marker for abuse of the nitrofuran drug nitrofurazone because the semicarbazide molecule may occur from other sources (Hoenicke et al., 2004; Sarnsonova et al., 2008; Bendall, 2009).

Nitrofurans are effective in the treatment of bacterial and protozoal infections in food-producing animals. Nitrofurans, such as furazolidone and furaltadone, continued to be used in food-producing animals after their prohibition. Although prohibited for use in food-producing animals in many countries, some nitrofuran products are likely to be available for use on solipeds. For example, products containing nitrofurantoin have been available for use in dogs, cats and horses for treatment of lower urinary tract infections (Lewis and Wilken, 1982; Bishop, 2005). However, only one non-compliant result for nitrofurans—nitrofurantoin in 2005—was reported for solipeds in the NRCPs 2005–2010.

Considering that nitrofurans have proven toxicity for humans, are effective as antibacterial treatments for solipeds, but that only one non-compliant result, dating from 2005, was found in NRCP testing, these substances currently are ranked as being of low potential concern.

(f) Chlorpromazine

Chlorpromazine is a sedative and is also used against motion sickness and as an anti-emetic in pets; its use in horses is not recommended as they can develop an ataxic reaction which results in excitation and violent episodes. Its use is banned in food-producing animals. No non-compliant results for chlorpromazine in solipeds were reported from the NRCP for the period 2005–2010.

Considering that no non-compliant results have been found in NRCP testing, chlorpromazine currently is ranked as being of low potential concern.

(g) Nitroimidazoles

The 5-nitroimidazoles, dimetridazole, metronidazole and ronidazole, are a group of drugs having antibacterial, anti-protozoal and anti-coccidial properties. Owing to the potential harmful effects of these drugs on human health—carcinogenicity, mutagenicity, genotoxicity and the occurrence of covalent binding to macromolecules of metabolites with an intact imidazole structure (EMEA, 1997b) —their use in food-producing animals is prohibited in the EU, USA, China and other countries.

One of the nitroimidazoles, metronidazole, has a clear therapeutic indication for horses (for life-threatening conditions) and thus might incidentally enter the food chain. However, no non-compliant results for nitroimidazoles in solipeds have been reported in NRCP testing.

Considering that nitroimidazoles have proven toxicity for humans and that they may be effective as antibacterial/anti-protozoal treatments for solipeds, but that no non-compliant results have been found in NRCP testing, nitroimidazoles currently are ranked as being of low potential concern.

(h) Colchicine

Colchicine is a plant alkaloid that has been used historically in veterinary medicine to treat papillomas and warts in cattle and horses by local injection at the affected area. A possible contamination of food with colchicine has been identified through consumption of *Colchicum autumnale* in forage (Hamscher et al., 2005). Colchicine is genotoxic and teratogenic and may have toxic effects on reproduction.

No non-compliant results for colchicine in solipeds have been reported from the NRCPs 2005–2010; however, it is probable that testing for this substance may not be included in monitoring programmes in many countries.

Considering that no non-compliant samples have been found over a number of years of NRCP testing, colchicine currently is ranked as being of low potential concern.

2.3.5.3.2. Veterinary medicinal products and feed additives above MRLs

In general, VMPs, except the substances allocated to Table 2 of Regulation (EU) No 37/2010, are categorised as being of low potential concern because they have all been subject to pre-marketing approval which specifies ADIs, and MRLs, with the aim of guaranteeing a high level of safety to the consumer. Where exceedances of MRLs are found in the NRCPs for solipeds (i.e. 6 non-compliant results for antibacterials out of the 3 603 tested samples; 1 non-compliant for anthelmintics out of the 1 083 tested samples, and 2 non-compliants for anticoccidials out of the 289 tested samples), these are typically of an occasional nature.

2.3.5.3.3. Contaminants: organochlorine pesticides, chemical elements (lead) and natural toxins

(a) Organochlorine compounds

Organochlorine pesticides, such as dichlorodiphenyltrichloroethane (DDT) and its metabolites, hexachlorocyclohexanes (HCHs), dieldrin and toxaphene have been assigned to the category of contaminants of low potential concern. Occurrence of residues of these substances has declined over the years, because of their long-standing ban, and relatively low levels in animal products can be expected, as shown by results from the NRCPs 2005–2010, which indicate that there were no non-compliant results for organochlorine pesticides.

(b) Chemical elements: lead

Lead is an environmental contaminant that occurs naturally and, to a greater extent, from anthropogenic activities such as mining and smelting and battery manufacturing (EFSA CONTAM Panel, 2010). Lead is a metal that occurs in organic and inorganic forms; the latter predominates in the environment. Human exposure is associated particularly with the consumption of cereal grains (except rice), cereal and cereal-based products, potatoes, leafy vegetables and tap water. The contribution of (soliped) meat and offal to human lead exposure is limited.

The results from the NRCPs for the 2005–2010 period show that, of the 4 728 soliped samples tested for chemical elements, 31 were non-compliant results for lead, some of which have been associated with local contamination sources.

Lead accumulates mainly in offals. Considering the low incidence of non-compliant results from the NRCPs and their association generally with local environmental contamination, lead currently is ranked as being of low potential concern.

(c) Natural toxins: mycotoxins and toxic plant secondary metabolites

(c.1) Mycotoxins

Mycotoxins comprise a chemically diverse group of secondary metabolites of moulds, which may induce intoxication in humans and animals following ingestion of contaminated food or feed materials.

Mycotoxins evaluated by the CONTAM Panel as undesirable contaminants in animal feeds, including aflatoxins (EFSA, 2004a), deoxynivalenol (EFSA, 2004b), fumonisins (EFSA, 2005a) and zearalenone (EFSA, 2004c), T-2 toxin (EFSA CONTAM Panel, 2011b), ergot alkaloids (EFSA CONTAM Panel, 2012), may pose a risk for animal health and productivity when present in feed materials that are used for solipeds over an extended period of time. However, even if residues of mycotoxins are occasionally detected in animal tissues, they do not contribute significantly to human exposure, which is mainly related to the consumption of cereal products, nuts and spices.

Considering that only one non-compliant result was reported in NRCPs for the 2005–2010 period and that mycotoxins in general have a limited transfer into edible tissues, mycotoxins currently are ranked as being of low potential concern.

(c.2) Toxic plant secondary metabolites

Plants used as feed materials may contain undesirable substances, such as toxic secondary metabolites and/or botanical impurities. The most commonly found toxic plant metabolites have been assessed by the CONTAM Panel within the framework of the re-evaluation of undesirable substances in animal feeds (implementation of Directive 2002/32/EC). The evaluations addressed plant metabolites such as glucosinolates (EFSA, 2008a), saponins (EFSA, 2009b), pyrrolizidine alkaloids (EFSA, 2007a, EFSA CONTAM Panel, 2011c), tropane alkaloids (EFSA, 2008b) and cyanogenic compounds (EFSA, 2007b) as well as a number of individual substances, such as theobromine (EFSA, 2008c), gossypol (EFSA, 2008d) and ricin (EFSA, 2008e). While for several of these substances potential concerns for animal health could be identified following ingestion with feed, none of these natural toxins appeared

to accumulate in edible tissues. The limited data on the kinetics of these metabolites does not preclude in all cases a transfer from the feed into animal tissues under certain circumstances of exposure. For example, numerous outbreaks of pyrrolizidine alkaloid-intoxication of horses (often attributed to ragwort and lucerne forage contaminated with *Senecio vulgaris*) have been reported (Pearson, 1991; Creeper et al., 1999; EFSA, 2007a; Crews and Anderson, 2009). However, none of the above toxic plant secondary metabolites appear to accumulate in edible tissues. Therefore, the CONTAM Panel concluded that it is unlikely that residues of these secondary plant metabolites in edible tissues constitute a risk for consumers. Such substances were therefore placed in the category of low potential concern within the current classification.

Recently, an increasing use of herbal remedies has been reported in equine medicine. Many of the herbal products contain biologically active substances that are also addressed in the list of undesirable plant metabolites. However, the remedies are given in low concentrations (lower than the larger amount that could be ingested with feed), and for a limited period. Although specific data are lacking, it seems unlikely that residues of these compounds may be found in edible tissues of slaughtered animals.

2.3.5.4. Substances classified in the negligible potential concern category

2.3.5.4.1. Prohibited substances: stilbenes, thyreostats, dapsone, chloroform and *Aristolochia* spp.

(a) Stilbenes

The toxicity of stilbenes is well established (for review see Waltner-Toews and McEwen, 1994), and this has led to their prohibition for use as growth promoters in animals in most countries, also based on their involvement in the baby food scandal in the late 1970s (Loizzo et al., 1984). In particular, diethylstilbestrol is a proven human genotoxic carcinogen (Group I IARC) (IARC, 2012), while sufficient evidence for hexestrol and limited evidence for dienestrol was found for carcinogenicity in animals (IARC, 1979). Diethylstilbestrol is associated with breast cancer in women who were exposed while pregnant. Adenocarcinoma in the vagina and cervix, squamous cell carcinoma of the cervix, cancer of the endometrium and cancer of the testis have all been associated with *in utero* exposure to diethylstilboestrol. In 1981, the use of stilbenes in all species of food-producing animals was prohibited in the European Community by Council Directive 81/602/EEC.

No non-compliant samples for stilbenes in soliped samples have been reported from the European NRCPs 2005–2010, indicating that abuse of stilbenes in solipeds in the EU is unlikely.

Considering that no non-compliant results have been found over a number of years of NRCP testing, stilbenes currently are ranked as being of negligible potential concern.

(b) Thyreostats

Thyreostats are a group of substances that inhibit the thyroid function, resulting in decreased production of the thyroid hormones triiodothyronine (T3) and thyroxine (T4). They are used in human and in non-food-producing animal medicine to deal with hyperthyroidism. The use of thyreostats for animal fattening is based on weight gain caused by filling of the gastrointestinal tract and retention of water in muscle tissues (Courtheyn et al., 2002). Synthetic thyreostats include thiouracil, methylthiouracil, propylthiouracil, methimazole, tapazole (methylmercaptoimidazole) and mercaptobenzimidazole (MBI). Use of synthetic thyreostats in food producing animals is prohibited in the EU since 1981 (Council Directive 81/602/EEC).

Thyreostats are considered to be carcinogenic and teratogenic; for example, an IARC evaluation reported inadequate evidence in humans, but limited evidence (in the case of methimazole) and sufficient evidence (in the case of thiouracil, methylthiouracil and propylthiouracil) in experimental animals for carcinogenicity (IARC, 2001).

There is no indication for use of thyreostats in solipeds. In addition, no non-compliant results for thyreostats in soliped samples have been reported from the European NRCPs 2005–2010, suggesting that the abuse of thyreostats is unlikely.

Considering that no non-compliant results have been found over a number of years of NRCP testing, thyreostats currently are ranked as being of negligible potential concern.

(c) Dapsone

Dapsone is a drug which has been used in both human and veterinary medicine, in human medicine for treatment of leprosy, malaria, tuberculosis and dermatitis; and in veterinary medicine as an intra-mammary treatment for mastitis, for oral treatment of coccidiosis and for intra-uterine treatment of endometriosis. Dapsone is included in Table 2 of Commission Regulation (EU) No 37/2010. Dapsone has a number of potentially harmful side effects in humans when given at therapeutic doses as a human medicine. More recently, the CVMP has reviewed the alleged mutagenicity of dapsone—in the context of its occurrence as an impurity in VMPs containing sulphonamides—and concluded that it is not genotoxic (CVMP, 2012), and EFSA has issued an opinion on the product as a food-packaging material (compound 15267), proposing an acceptable level of 5 mg/kg food (EFSA, 2005b).

No non-compliant results for dapsone in solipeds have been reported from the NRCPs 2005–2010. However, a review of testing carried out in MSs during 2008 by the Community Reference Laboratory AFSSA (Agence Française de Sécurité Sanitaire des Aliments, Fougères, France) found that testing for dapsone in solipeds was carried out in only two countries.

In the absence of information on the occurrence of non-compliant results and in consideration of the recent toxicological re-evaluations for this substance, dapsone currently is ranked as being of negligible potential concern.

(d) Chloroform and plant remedies containing *Aristolochia*

to the negligible potential concern category also are assigned the prohibited substances, chloroform and plant remedies containing *Aristolochia* species, as these are not relevant to treatment of solipeds and there is no evidence for illicit use or abuse of these substances in solipeds.

2.3.5.4.2. Veterinary medicinal products (VMPs) below MRLs: carbamates and pyrethroids, sedatives

VMPs that may be used in domestic solipeds but with no evidence for residues above MRLs being found in monitoring programmes as well as those VMPs irrelevant for solipeds are ranked as being of negligible potential concern.

(a) Carbamates and pyrethroids

Carbamates and pyrethroids may be used in animals as ectoparasiticides and in animal houses for control of environmental infections, such as lice eggs. Although such compounds are lipophilic in nature and may be stored in fat and in organs such as the liver, they are characterised by a relatively rapid excretion. There are no recent incidents of non-compliant results reported in NRCP testing for domestic solipeds during the period 2005–2010, resulting in these substances being assigned to the category of negligible potential concern.

(b) Sedatives

A range of sedative substances including barbiturates, promazines, xylazine and ketamine, are licensed for use in animals for sedation and analgesia during surgical procedures or for euthanasia. Animals euthanised with these substances are not allowed to enter the food chain. Owing to their rapid excretion, these substances generally do not have detectable residues in muscle and so do not have MRLs registered in the EU. They might be used during transport of animals to slaughter or even during working the animals. However, no non-compliant results have been reported for the 626

soliped samples analysed under the NRCPs (2005–2010), resulting in these substances being assigned to the category of negligible potential concern.

2.3.5.4.3. Contaminants: organophosphorus compounds, chemical elements and dyes

(a) Organophosphorus compounds

Results from the NRCPs from 2005–2010 indicate that there were no non-compliant results for the category of organophosphorus compounds in solipeds. In addition, considering their generally short half-life, these compounds are allocated to the category of negligible potential concern.

(b) Chemical elements

Besides the heavy metals cadmium and lead discussed previously, other chemical elements such as copper, selenium and zinc need to be considered. These elements are used as feed supplements in various farm animal species. Use in horses is generally limited to the application of selenium (selenium methionine or selenium-enriched yeasts) as a feed supplement and in some cases as an injectable formulation. The correct use of these supplements cannot be guaranteed, but their distribution and effective excretion make it unlikely that significant residues occur in horse meat. These substances currently are ranked as being of negligible potential concern.

(c) Dyes

There are no indications for use of dyes such as (leuco-)malachite green in domestic solipeds. Testing of domestic solipeds for this group of substances is not required under Council Directive 96/23/EC.

A summary of the outcome of the ranking is presented in Table 7.

Table 7: Ranking of chemical residues and contaminants in domestic solipeds based on predefined criteria and taking into account the findings from the NRCPs for the period 2005–2010

Group / Potential concern category	Prohibited substances	VMPs and licensed feed additives	Contaminants
Category 1 **Negligible potential concern**	• Stilbenes • Thyreostats • Dapsone • Chloroform • *Aristolochia* spp.	• VMPs below MRLs	• Organophosphorus compounds • Chemical elements (other than cadmium and lead) • Dyes
Category 2 **Low potential concern**	• Steroids • Resorcylic acid lactones • Beta-agonists • Chloramphenicol • Nitrofurans • Chlorpromazine • Nitroimidazoles • Colchicine	• VMPs exceeding MRLs	• Organochlorine pesticides • Natural toxins (mycotoxins and PSMs) • Chemical elements (lead)
Category 3 **Medium potential concern**	No substances ranked in this category		
Category 4 **High potential concern**	• Phenylbutazone		• Chemical elements (cadmium)

MRL, maximum residue limit; NRCP, national residue control plan; PSM, plant secondary metabolite; VMP, veterinary medicinal product.

2.3.5.5. Future aspects

The ranking into specific categories of potential concern of prohibited substances, VMPs and contaminants presented in this section applies to horses, donkeys and their cross-breeds and it is based on current knowledge regarding the toxicological profiles, usage in solipeds and occurrence as residues or contaminants across Europe, as demonstrated by the data from the NRCPs for the 2005–2010 period. Where changes in any of these factors occur, the ranking might need amendment.

2.3.5.5.1. New hazards

Another element of future aspects is the issue of 'new hazards'. In this context, 'new hazards' are defined as compounds that have been identified as anthropogenic chemicals in food-producing animals and derived products and in humans and for which occurrence data are scarce and which may not be systematically covered by the NRCPs. Examples are polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans (together often termed 'dioxins'), dioxin-like polychlorinated biphenyls (DL-PCBs), non dioxin-like polychlorinated biphenyls (NDL-PCBs), brominated flame retardants, such as polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), or perfluorinated compounds, such as perfluorooctane sulphonate (PFOS) and perfluorooctanoic acid (PFOA).

(a) Dioxins[44]

Dioxins are persistent organochlorine contaminants that are not produced intentionally, have no targeted use, but are formed as unwanted and often unavoidable by-products in a number of thermal and industrial processes. Because of their low water solubility but high lipophilic properties, they bioaccumulate in the food chain and are stored in fatty tissues of animals and humans. The major

[44] The term 'dioxins' used in this opinion refers to the sum of polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs).

pathway to human dioxin exposure is via consumption of food of animal origin which generally contributes more than 80 % of the total daily dioxin intake (EFSA, 2010b). A number of incidents in the past 15 years were caused by contamination of feed with dioxins. Examples are feeding of contaminated citrus pulp pellets or incorrectly dried bakery by-products, kaolinitic clay containing potato peels or mixing of compound feed with contaminated fats or fatty acids intended for industrial purposes.

All these incidents were caused by grossly negligent or criminal actions and led to widespread contamination of feed and subsequently to elevated dioxin levels in the animals and the foodstuffs produced from them. Besides these incidents, the keeping of solipeds outdoors may lead to elevated dioxin levels, especially in areas with substantial environmental contamination. Limited literature data show considerable dioxin levels in horse meat (Focant et al., 2002). The authors report a mean dioxin level for 12 horse meat samples of 7.82 pg WHO-TEQ_{1998}/g fat. This is considerably higher than the mean levels reported in the same study for meat from sheep (n=2), beef (n=25), pork (n=34) and chicken (n=48), being 1.55, 1.56, 0.17 and 0.35 pg WHO-TEQ_{1998}/g fat, respectively. Somewhat lower dioxin levels in meat from horses, mules, asses or hinnies were reported by several MSs to EFSA following a call for data. Levels in 11 meat samples ranged from 0.16 to 3.94 (mean 0.82, median 0.57) pg WHO-TEQ_{2005}/g fat. Dioxin levels in 16 fat samples from horses, mules, asses or hinnies ranged from 0.16 to 16.85 (mean 2.82, median 0.91) pg WHO-TEQ_{2005}/g fat. For two liver samples, dioxin concentrations of 3.85 and 14.76 pg WHO-TEQ_{2005}/g fat were reported (EFSA, 2012c). The results are all expressed as upper bound concentrations.

Dioxins have a long half-life and accumulate in various tissues. The findings of elevated levels in food are of public health concern due to potential for effects on liver, thyroid, immune function, reproduction and neurodevelopment (EFSA, 2005c, 2010b). A report 'Monitoring of Dioxins and PCBs in Food and Feed' (EFSA, 2012c) estimated that between 1.0 % and 52.9 % of individuals were exposed above the tolerable weekly intake (TWI) of 14 pg toxic equivalents (TEQ)/kg body weight for the sum of dioxins and DL-PCBs. In addition to milk and dairy products and fish and seafood, meat and meat products also contributed considerably to total exposure.

Based on the high toxicity, widespread occurrence in the environment and limited data on occurrence in solipeds, dioxins deserve attention and should be considered for inclusion in the NRCPs.

(b) Dioxin-like polychlorinated biphenyls

In contrast to dioxins, PCBs had widespread use in numerous industrial applications, generally in the form of complex technical mixtures. Due to their physico-chemical properties, such as non-flammability, chemical stability, high boiling point, low heat conductivity and high dielectric constants, PCBs were widely used in industrial and commercial closed and open applications. They were produced for over four decades, from 1929 onwards until they were banned, with an estimated total world production of 1.2–1.5 million tonnes. According to Council Directive 96/59/EC[45], MS shall take the necessary measures to ensure that used PCBs are disposed of and equipment containing PCBs are decontaminated or disposed of at the latest by the end of 2010. Earlier experience has shown that illegal practices of PCB disposal may occur, resulting in considerable contamination of animals and foodstuffs of animal origin. Also, PCBs have been used in paints and sealants and, therefore, may be present at farms.

Based on structural characteristics and toxicological effects, PCBs can be divided into two groups. One group consists of 12 congeners that can easily adopt a coplanar structure and have the ability to bind to the Ah-receptor, thus showing toxicological properties similar to dioxins (effects on liver, thyroid, immune function, reproduction and neuro-development). Therefore, this group of PCBs is called ''dioxin-like PCBs'' (DL-PCBs). The other PCBs do not show dioxin-like toxicity and have a

[45] Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT). OJ L 243, 24.9.1996, p. 31-35.

different toxicological profile, in particular with respect to effects on the developing nervous system and neurotransmitter function. This group of PCBs is called ''non dioxin-like PCBs'' (NDL-PCBs).

As for dioxins, the keeping of solipeds outdoors may lead to elevated levels of DL-PCBs. For example, a study conducted in Belgium in 2002 indicated that horse meat, on average, contained higher levels of several DL-PCBs than samples from sheep, beef, pigs and chicken (Focant et al., 2002).

DL-PCB concentrations in meat, fat and liver from horses, mules, asses or hinnies have been reported by several MSs to EFSA following a call for data. Levels in 11 meat samples ranged from 0.01 to 12.81 (mean 1.80, median 0.80) pg WHO-TEQ_{2005}/g fat. DL-PCB levels in 16 fat samples from horses, mules, asses or hinnies ranged from 0.01 to 18.88 (mean 4.73, median 2.65) pg WHO-TEQ_{2005}/g fat. For two liver samples, DL-PCB concentrations of 1.26 and 4.09 pg WHO-TEQ_{2005}/g fat were reported (EFSA, 2012c). The results are all expressed as upper bound concentrations.

As DL-PCBs, in general, show a comparable lipophilicity, bioaccumulation, toxicity and mode of action to dioxins (EFSA, 2005c), these two groups of environmental contaminants are regulated together in European legislation and are considered together in risk assessments.

Based on the high toxicity, widespread occurrence in the environment and limited data on occurrence in solipeds, DL-PCBs deserve attention and should be considered for inclusion in the NRCPs.

(c) Non dioxin-like PCBs (NDL-PCBs)

The NDL-PCBs show a different toxicological profile to the DL-PCBs. In 2005, the CONTAM Panel undertook a risk assessment on NDL-PCBs in food (EFSA, 2005c). In the final conclusion, the CONTAM Panel stated that no health-based guidance value for humans can be established for NDL-PCBs because simultaneous exposure to dioxin-like compounds hampers the interpretation of the results of the toxicological and epidemiological studies, and the database on effects of individual NDL-PCB congeners is rather limited. There are, however, indications that subtle developmental effects, caused by NDL-PCBs, DL-PCBs, or polychlorinated dibenzo-*p*-dioxins/polychlorinated dibenzofurans alone, or in combination, may occur at maternal body burdens that are only slightly higher than those expected from the average daily intake in European countries. In its risk assessment the CONTAM Panel decided to use the sum of the six PCB congeners –28, -52, -101, -138, -153 and -180 as the basis for their evaluation, because these congeners are appropriate indicators for different PCB patterns in various sample matrices and are most suitable for a potential concern assessment of NDL-PCBs on the basis of the available data. Moreover, the Panel noted that the sum of these six indicator PCBs represents about 50 % of total NDL-PCBs in food (EFSA, 2005c).

Concentrations for the sum of these six NDL-PCBs in meat, fat and liver from horses, mules, asses or hinnies have been reported by several MSs to EFSA following a call for data. Levels in 11 meat samples ranged from 1.20 to 15.10 (mean 5.19, median 2.64) µg/kg fat. NDL-PCB levels in 16 fat samples from horses, mules, asses or hinnies ranged from 1.74 to 263.2 (mean 33.3, median 16.4) µg/kg fat. For two liver samples, NDL-PCB concentrations of 2.90 and 5.75 µg/kg fat were reported (EFSA, 2012c). The results are all expressed as upper bound concentrations.

As NDL-PCBs bioaccumulate in the food chain and, considering the potential for improper disposal practices of technical PCB products, they deserve attention and should be considered for broader inclusion in the NRCPs.

(d) Polybrominated diphenyl ethers

In 2011, EFSA undertook a risk assessment on PBDEs in food (EFSA CONTAM Panel, 2011d). PBDEs are additive flame retardants which are applied in plastics, textiles, electronic castings and circuitry. PBDEs are ubiquitously present in the environment and likewise in biota and in food and

feed. Eight congeners were considered by the CONTAM Panel to be of primary interest: BDE-28, -47, -99, -100, -153, -154, -183 and -209. The highest dietary exposure is to BDE-47 and -209. Toxicity studies have been carried out with technical PBDE mixtures or individual congeners. The main targets were the liver, thyroid hormone homeostasis and the reproductive and nervous system. PBDEs are not genotoxic. The CONTAM Panel identified effects on neurodevelopment as the critical endpoint, and derived benchmark doses (BMDs) and their corresponding lower 95 % confidence limits for a benchmark response of 10 %, the $BMDL_{10}$s, for a number of PBDE congeners: BDE-47, 309 µg/kg body weight (b.w.); BDE-99, 12 µg/kg b.w.; BDE-153, 83 µg/kg b.w.; BDE-209, 1700 µg/kg b.w. Due to the limitations and uncertainties in the current database, the Panel concluded that it was inappropriate to use these benchmark dose lower confidence limits (BMDLs) to establish health based guidance values, and instead used a margin of exposure (MOE) approach for the health risk assessment. Since elimination characteristics of PBDE congeners in animals and humans differ considerably, the Panel used the body burden as starting point for the MOE approach. The CONTAM Panel concluded that for BDE-47, -153 and -209 current dietary exposure in the EU does not raise a health concern. For BDE-99 there is a potential health concern with respect to current dietary exposure. The contribution of meat from solipeds to the total human exposure is currently not known.

As these compounds bioaccumulate in the food chain, PBDEs deserve attention and should be considered for inclusion in the NRCPs.

(e) Hexabromocyclododecanes (HBCDDs)

In 2011, EFSA delivered a risk assessment on HBCDDs in food (EFSA CONTAM Panel, 2011e). HBCDDs are additive flame retardants primarily used in expanded and extruded polystyrene applied as construction and packing materials, and in textiles. Technical HBCDD consists predominantly of three stereoisomers (α-, β- and γ-HBCDD). Also δ- and ε-HBCDD may be present but at very low concentrations. HBCDDs are present in the environment and likewise in biota and in food and feed. Data from the analysis of HBCDDs in 1 914 food samples were provided to EFSA by seven European countries, covering the period from 2000 to 2010. The CONTAM Panel selected α-, β- and γ-HBCDD to be of primary interest. Since all toxicity studies were carried out with technical HBCDD, a risk assessment of individual stereoisomers was not possible. Main targets were the liver, thyroid hormone homeostasis and the reproductive, nervous and immune systems. HBCDDs are not genotoxic. The CONTAM Panel identified neurodevelopmental effects on behaviour as the critical endpoint, and derived a benchmark dose lower confidence limit for a benchmark response of 10 % ($BMDL_{10}$) of 0.79 mg/kg b.w. Due to the limitations and uncertainties in the current data base, the CONTAM Panel concluded that it was inappropriate to use this BMDL to establish a health based guidance value, and instead used an MOE approach for the health risk assessment of HBCDDs. Since elimination characteristics of HBCDDs in animals and humans differ, the Panel used the body burden as starting point for the MOE approach. Based on the available data, the CONTAM Panel concluded that current dietary exposure to HBCDDs in the EU does not raise a health concern.

As the current knowledge about the occurrence and the levels of HBCDDs in edible tissues of solipeds are lacking, inclusion in the NRCPs should be considered.

(f) Perfluorinated compounds (PFCs)

Perfluorinated compounds (PFCs), such as PFOS, PFOA and others, have been widely used in industrial and consumer applications including stain- and water-resistant coatings for fabrics and carpets, oil-resistant coatings for paper products approved for food contact, fire-fighting foams, mining and oil well surfactants, floor polishes, and insecticide formulations. A number of different perfluorinated organic compounds have been found widely in the environment. In 2008, EFSA delivered a risk assessment on PFOS and PFOA in food (EFSA, 2008f). The CONTAM Panel established a tolerable daily intake (TDI) for PFOS of 150 ng/kg b.w. per day and a TDI for PFOA of 1.5 µg/kg b.w. per day. Some few data indicated the occurrence of PFOS and PFOA in meat samples. However, due to the low number of data, it has not been possible to perform an assessment of the relative contribution from different foodstuffs to human exposure to PFOS and PFOA. A recent study

where contaminated feed was fed to food-producing animals demonstrated the transfer of PFOS, PFOA and various other perfluorinated compounds with different chain lengths into meat and various organs of cows, pigs, sheep and chicken (Ehlers, 2012).

As perfluorinated compounds have found widespread use and have ubiquitous distribution in the environment, and since representative data on their occurrence in meat of solipeds are missing, an intensified monitoring of these compounds in tissues, as well as in feed, should be considered.

3. TOR 2: Strengths and weaknesses of the current meat inspection methodology

In the light of the existing Regulations and the daily practice of the control of residues/chemical substances in solipeds, the strengths and weaknesses of the current meat inspection methodology can be summarised as follows:

3.1. Strengths of the current meat inspection methodology for chemical hazards

- Residue testing is based on common standards for method performance and interpretation of results (Commission Decision 2002/657/EC), laboratory accreditation (ISO/IEC 17025) and quality assurance schemes (QAS). The NRCPs are supported by a network of EU and national reference laboratories and by research in the science of residue analysis that serves to provide state-of-the-art testing systems for control of residues and contaminants (see Annex A).

- The system for issuing of single lifetime identification documents (passports), where it is entirely implemented and properly enforced, should allow for information on traceability, changes of ownership, and follow-up procedures.

3.2. Weaknesses of the current meat inspection methodology for chemical hazards

- Presence of chemical hazards generally cannot be detected by current *ante-*/*post-mortem* meat inspection procedures.

- Although legally designated as food-producing animals, solipeds are commonly regarded as companion/sport/working animals and thus some animals may receive treatments that are not permitted for food-producing animals.

- The single lifetime identification document (passport) system currently is not properly applied/enforced throughout the EU. This may result in animals treated as non-food-producing animals entering the food chain.

- Follow-up actions subsequent to the identification of non-compliant results is difficult due to the poor traceability and, in many cases, due to the fact that frequently individual animals are presented for slaughter. Solipeds come to slaughter at variable ages (up to 30 years old), may have been reared on a number of different holdings and in small numbers. The animals often come from mixed holdings rearing both food- and non- food producing solipeds, and sometimes following lengthy transport prior to slaughter. All these factors may result in the FCI for these animals over their entire lifetime being incomplete or difficult to obtain and may compromise traceability.

- At present, the level of sampling and the substances to be tested for is poorly defined across the EU. This is reflected in the variability of sampling intensity between MSs.

4. TOR 3: New hazards

Current monitoring of residues and contaminants in solipeds is based on Council Directive 96/23/EC. In turn, risk ranking, as presented under TOR 1, is also based largely on the chemical substances listed in Council Directive 96/23/EC. The outcome of the ranking showed that only a small number of compounds are considered to constitute a high potential concern for consumers.

Considering the recent information available from the re-assessment of undesirable substances in the food chain, covered by more recent EFSA opinions from the CONTAM Panel, additional compounds have been identified that require attention. Prominent examples of such substances are dioxins and DL-PCBs, as they bioaccumulate in the food chain and have a toxicological profile that points towards public health concerns even at low (residue) concentrations. In addition, it has been shown that these substances are found in edible tissues of solipeds (see Section 2.3.5.5.1). Other halogenated substances, such as brominated flame retardants, including polybrominated diphenylethers (PBDEs) as well as hexabromocyclododecanes (HBCDDs), and perfluorinated compounds (PFCs,) such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), have a different toxicological profile. They bioaccumulate in the food chain and deserve attention, as currently the knowledge about the prevalence and level of residues of these compounds in edible tissues of solipeds is limited. Inclusion of these various substances in the NRCPs should be considered to support forthcoming decisions on whether or not these substances require continued monitoring either in feed materials and/or in slaughter animals. (Note: further detailed information on each of these compounds is presented in Section 2.3.5.5.1.)

Due to the nature of the husbandry systems applied and the age to which solipeds may be kept they are more likely to have a build-up of persistent environmental contaminants than some other farm animals.

5. TOR 4: Adaptation of inspection methods

A more robust and reliable identification system is needed to improve the traceability of domestic solipeds. Individual lifetime identification of domestic solipeds and of the 'passport' system (Commission Decision 2000/68/EC,[46] Commission Regulation (EC) No 504/2008) should be strengthened, implemented and enforced throughout the EU.

For solipeds, the FCI should provide information on the specific environmental conditions on the farms where the animals are reared as well as the individual animal history, including treatments with substances other than those listed in Table 1 of the Annex to Regulation (EU) No 37/2010 or the 'essential substances' listed in Annex to Commission Regulation (EU) No 122/2013. It is recommended that sampling of solipeds should be based on the risk of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied.

The high number of non-compliant results for cadmium in solipeds is a matter of concern. There is need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants.

VMPs can be licensed for food-producing horses or restricted to use on non-food-producing horses. However, VMPs not licensed for use in food-producing animals have been found in horse meat. For example, phenylbutazone is not authorised for use in food-producing animals because of safety concerns, but it may be legally administered to non-food-producing solipeds. Owing to these safety concerns and considering that this compound has been found in edible tissues of solipeds in most years of the NRCP 2005–2010, testing for phenylbutazone (including its metabolites) should be specifically included in the NRCPs for solipeds.

Substances listed in Commission Regulation (EU) No 122/2013 (denoted as 'substances essential for the treatment of Equidae') are allowed for soliped animals by derogation with a withdrawal period of six months. Where relevant, based on the toxicological profile and kinetic properties, priority substances from this list should be identified for inclusion in testing in NRCPs to check compliance with withdrawal periods.

[46] Commission Decision 2000/68/EC of 22 December 1999 amending Commission Decision 93/623/EEC and establishing the identification of equidae for breeding and production. OJ L 23, 28.1.2000, p. 72–5.

As the sampling intensity for solipeds varies substantially between MSs, a minimum number of samples, proportional to the production (slaughtered animals) for each MS, should be specified in NRCPs in order to ensure an equal level of control across the EU.

In addition, there is a need to develop new approaches to testing. Recent developments in chemical analytical techniques allow the simultaneous measurement of a broad range of substances. Application of such validated methods for multi-residue analyses, comprising veterinary drugs, pesticides and natural and environmental contaminants, should be encouraged. Analytical techniques covering multiple analytes and biologically based testing approaches should be encouraged and incorporated into residue controls.

Finally, it should be noted that any measures taken to improve the efficacy of meat inspection protocols also need to address the compliance of imports to the EU with these strategies.

CONCLUSIONS AND RECOMMENDATIONS

This section contains conclusions derived from the information discussed in the document, together with recommendations for improvements to meat inspection with regard to chemical hazards within the EU.

TOR 1. To identify and rank the main risks for public health that should be addressed by meat inspection at European Union level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e.g. breeding compared to fattening animals).

CONCLUSIONS

- As a first step in the identification and ranking of chemical substances of potential concern, the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) considered the substances listed in Council Directive 96/23/EC and evaluated the outcome of the National Residue Control Plans (NRCP) for the period 2005–2010. The CONTAM Panel noted that 2.28 % of the total number of results was non-compliant for one or more substances listed in Council Directive 96/23/EC. The available aggregated data indicate the number of samples that were non-compliant with current EU/national legislation. However, in the absence of substance-specific information, such as the tissues used for residue analysis and the actual concentration of a residue or contaminant measured, these data do not allow for a reliable assessment of consumer exposure.

- Other criteria used for the identification and ranking of chemical substances of potential concern included the identification of substances that are found in other testing programmes, that bio-accumulate in the food chain, substances with a toxicological profile of concern, and the likelihood that a substance under consideration will occur in equine carcasses. Taking into account these criteria, the individual compounds were ranked into four categories denoted as being of high, medium, low and negligible potential concern.

- The highest proportion of non-compliant samples overall (6.25 %) is for Group B3 substances, contaminants (particularly cadmium) representing exceedances of the Maximum Levels/Maximum Residue Limits (MLs/MRLs) specified for these substances. For Group A, prohibited substances (0.16 %), and for Group B1/B2 substances, veterinary medicinal products (VMPs) (0.40 %), the proportions of non-compliant samples is much lower, representing largely illicit use and exceedances of the MRLs specified for VMPs, respectively.

- Phenylbutazone is ranked as being of high potential concern owing to its toxicological properties and proven human toxicity and because of the occurrence of non-compliant results in NRCP testing.

- The environmental contaminant, cadmium, is ranked as being of high potential concern because of its toxicological properties and because of the occurrence of non-compliant results in NRCP testing. All other compounds listed in Council Directive 96/23/EC are ranked as being of low or negligible potential concern owing to the toxicological profile of these substances at residue levels in edible tissues, or to the very low or non-occurrence of non-compliant results in the NRCPs 2005–2010. Potentially higher exposure of consumers to these substances from horse meat takes place only incidentally, as a result of non-compliance with known and regulated procedures. However, baseline monitoring for the occurrence of substances currently ranked as being of low or negligible potential concern in solipeds is desirable.

- The CONTAM Panel emphasises that this ranking into specific categories of potential concern applies to horses, donkeys and their cross-breeds and it is based on current knowledge regarding the toxicological profiles, usage in solipeds, and occurrence as residues across the EU, as demonstrated by the data from the NRCPs for the 2005–2010 period.

RECOMMENDATIONS

- Future monitoring programmes should be risk based, taking into account the ranking of chemical compounds into categories of potential concern.

- Regular updating of the ranking of chemical compounds in domestic solipeds as well as of the sampling plans should occur, taking into account any new information regarding the toxicological profile of chemical residues and contaminants, usage in solipeds and occurrence of individual substances as residues and contaminants in domestic solipeds.

TOR 2. To assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at *ante-mortem* or *post-mortem* inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.

CONCLUSIONS

The strengths of the current meat inspection methodology for chemical hazards are as follows:

- The current procedures for sampling and testing are a mature system, in general well established and coordinated, including follow-up actions subsequent to the identification of non-compliant samples.

- The system of issuing of single lifetime identification documents (passports), where it is entirely implemented and properly enforced, should allow for information on traceability, changes of ownership, and follow-up procedures.

The weaknesses of the current meat inspection methodology for chemical hazards are as follows:

- Presence of chemical hazards generally cannot be detected by current *ante-/post- mortem* meat inspection procedures.

- Solipeds are commonly regarded as companion/sport/working animals and thus some animals may receive treatments that are not permitted for food-producing animals.

- The single lifetime identification document (passport) system currently is not properly applied/enforced throughout the EU. This may result in animals treated as non-food-producing animals entering the food chain.

- Solipeds come to slaughter at variable ages (up to 30 years old) and may have been reared on a number of different holdings and in low numbers. The animals often come from mixed holdings rearing both food-producing and non-food-producing solipeds, and sometimes following lengthy transport prior to slaughter. All these factors may result in the FCI for these animals over their entire lifetime being incomplete or difficult to obtain, and this may compromise traceability.

- At present, the level of sampling and the substances to be tested for is poorly defined across the EU. This is reflected in the variability of sampling intensity among MSs.

RECOMMENDATION

- Meat inspection systems for chemical residues and contaminants should be less prescriptive and should be more risk and information based, with sufficient flexibility to adapt the residue monitoring programmes to the results of testing.

TOR 3. If new hazards currently not covered by the meat inspection system (e.g. *Salmonella, Campylobacter*) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.

CONCLUSIONS

- 'New hazards' are defined as compounds that have been identified as anthropogenic chemicals in food-producing animals and derived products and in humans and for which occurrence data in solipeds are scarce and which may not be systematically covered by the NRCPs. Examples are polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans (together often termed "dioxins"), dioxin-like PCBs (DL-PCBs), non dioxin-like PCBs (NDL-PCBs), brominated flame retardants, such as polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), and perfluorinated compounds, such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA).

- Owing to the nature of the husbandry systems and the age to which solipeds may be kept, they are more likely to have a build-up of persistent environmental contaminants than some other farm animals.

RECOMMENDATION

- Control programmes for residues and contaminants should include ''new hazards'' and take into account information from environmental monitoring programmes which identify chemical hazards to which animals may be exposed.

TOR 4. To recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria. When appropriate, food chain information should be taken into account.

CONCLUSIONS

- For solipeds, the FCI should provide information on the specific environmental conditions on the farms where the animals are reared as well as the individual animal history, including treatments with substances other than those listed in Table 1 of the Annex to Regulation (EU) No 37/2010 and those 'essential substances' listed in the Annex to Commission Regulation (EU) No 122/2013.

- It is a matter of concern that a relatively large number of samples were non-compliant for the NSAID phenylbutazone and for the environmental contaminant cadmium.

RECOMMENDATIONS

- A more robust and reliable identification system is needed to improve the traceability of domestic solipeds. Individual lifetime identification of domestic solipeds and the 'passport' system (Commission Decision 2000/68/EC, Commission Regulation (EC) No 504/2008) should be strengthened, implemented and enforced throughout the EU.

- Sampling of solipeds should be based on the types and likelihood of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied.

- For cadmium, which occurs at high prevalence above MLs in soliped samples, there is need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants.

- Phenylbutazone, which is not licensed for use in food-producing solipeds, should be specifically included in the NRCPs for solipeds.

- From the 'essential substances' listed in Commission Regulation (EU) No 122/2013, allowed for use in soliped animals by derogation with a withdrawal period of six months, priority substances should be identified for inclusion in testing in NRCPs to check compliance with withdrawal periods.

- As the sampling intensity for solipeds varies substantially among MSs, a minimum number of samples, proportional to the production (slaughtered animals) for each MS, should be specified in NRCPs in order to ensure an equal level of control across the EU.

- The development of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into feed control and chemical residues and contaminants testing in the NRCPs.

REFERENCES

Bendall JG, 2009. Semicarbazide is non-specific as a marker metabolite to reveal itrofurazone abuse as it can form under Hofmann conditions. Food Additives and Contaminants Part A, 26, 47–56.

Bishop Y, 2005. The veterinary formulary. Sixth edition. Pharmaceutical Press, London, UK, 162 pp.

Bliss DH, 1989. The professional handbook of the donkey. Second edition. Ed. Svendsen ED, The Donkey Sanctuary, Sidmouth, UK, 95 pp.

Carraro L, Ferraresso S, Cardazzo B, Romualdi C, Montesissa C, Gottardo F, Patarnello T, Castagnaro M and Bargelloni L, 2009. Expression profiling of skeletal muscle in young bulls treated with steroidal growth promoters. Physiological Genomics, 38, 138–148.

Chaplin S, 1986. Bone marrow depression due to mianserin, phenylbutazone, oxyphenbutazone and chloramphenicol. Part I. Adverse Drug Reactions and Acute Poisoning Review, 5, 97–136.

Courtheyn D, Le Bizec B, Brambilla G, De Brabander HF, Cobbaert E, Van de Wiele M, Vercammen J and De Wasch K, 2002. Recent developments in the use and abuse of growth promoters. Analytica Chimica Acta, 473, 71–82.

Creeper JH, Mitchell AA, Jubb TF and Colegate SM, 1999. Pyrrolizidine alkaloid poisoning of horses grazing a native heliotrope (*Heliotropium ovalifolium*). Australian Veterinary Journal, 77, 401–402.

Crews C and Anderson WAC, 2009. Detection of ragwort alkaloids in toxic hay by liquid chromatography/time-of-flight mass spectrometry. Veterinary Record, 165, 568–569.

CVMP (Committee for Medicinal Products for Veterinary Use), 2012. CVMP assessment report under Article 30(3) of Regulation (EC) No 726/2004 for dapsone as an impurity in veterinary medicinal products containing sulphamethoxazole or other sulphonamides, 12 July 2012. EMA/CVMP/392271/2012. Available online http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/02/WC500138474.pdf

Dodman N, Blondeau N and Marini AM, 2010. Association of phenylbutazone usage with horses for slaughter: a public heath risk. Food and Chemical Toxicology, 48, 1270–1274.

EFSA (European Food Safety Authority), 2004a. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to aflatoxin B_1 as undesirable substance in animal feed. The EFSA Journal 2004, 39, 1–27.

EFSA (European Food Safety Authority), 2004b. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to deoxynivalenol (DON) as undesirable substance in animal feed. The EFSA Journal 2004, 73, 1–42.

EFSA (European Food Safety Authority), 2004c. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to zearalenone as undesirable substance in animal feed. The EFSA Journal 2004, 89, 1–35.

EFSA (European Food Safety Authority), 2005a. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to fumonisins as undesirable substances in animal feed. The EFSA Journal 2005, 235, 1–32.

EFSA (European Food Safety Authority), 2005b. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 9th list of substances for food contact materials. The EFSA Journal 2005, 248, 1–16.

EFSA (European Food Safety Authority), 2005c. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to the presence of non dioxin-like polychlorinated biphenyls (PCB) in feed and food. The EFSA Journal 2005, 284, 1–137.

EFSA (European Food Safety Authority), 2007a. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission related to pyrrolizidine alkaloids as undesirable substances in animal feeds. The EFSA Journal 2007, 447, 1–51.

EFSA (European Food Safety Authority), 2007b. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to cyanogenic compounds as undesirable substances in animal feed. The EFSA Journal 2007, 434, 1–67.

EFSA (European Food Safety Authority), 2008a. Glucosinolates as undesirable substances in animal feed—Scientific opinion of the Panel of Contaminants in the Food Chain. The EFSA Journal 2008, 590, 1–76.

EFSA (European Food Safety Authority), 2008b. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on tropane alkaloids (from *Datura* sp.) as undesirable substances in animal feed. The EFSA Journal 2008, 691, 1–55.

EFSA (European Food Safety Authority), 2008c. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on theobromine as undesirable substances in animal feed. The EFSA Journal 2008, 725, 1–66.

EFSA (European Food Safety Authority), 2008d. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on gossypol as undesirable substances in animal feed. The EFSA Journal 2008, 908, 1–55.

EFSA (European Food Safety Authority), 2008e. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on ricin (from *Ricinus communis*) as undesirable substances in animal feed. The EFSA Journal 2008, 726, 1–38.

EFSA (European Food Safety Authority), 2008f. Opinion of the Scientific Panel on Contaminants in the Food chain on Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts. The EFSA Journal 2008, 653, 1–131.

EFSA (European Food Safety Authority), 2009a. Scientific Opinion of the Panel of Contaminants in the Food Chain on cadmium in food. The EFSA Journal 2009, 980, 1–139.

EFSA (European Food Safety Authority), 2009b. Scientific Opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on saponins in *Madhuca longifolia* L. as undesirable substances in animal feed. The EFSA Journal 2009, 979, 1–36.

EFSA (European Food Safety Authority), 2010. Results of the monitoring of dioxin levels in food and feed. EFSA Journal 2010;8(3):1385, 36 pp.

EFSA (European Food Safety Authority), 2012a. Technical hearing on meat inspection of domestic solipeds. Supporting Publications: EN-375, 13 pp.

EFSA (European Food Safety Authority), 2012b. Cadmium dietary exposure in the European population. EFSA Journal 2012;10(1): 2551, 37 pp.

EFSA (European Food Safety Authority), 2012c. Update of the monitoring of dioxins and PCBs levels in food and feed. EFSA Journal 2012;10(7):2832, 82 pp.

EFSA and EMA (European Food Safety Authority and European Medicines Agency), 2013. Joint Statement of EFSA and EMA on the presence of residues of phenylbutazone in horse meat. EFSA Journal 2013;11(4):3190, 45 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010. Scientific Opinion on lead in food. EFSA Journal 2010;8(4):1570, 151 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011a. Scientific Opinion on tolerable weekly intake for cadmium. EFSA Journal 2011;9(2):1975, 19 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011b. Scientific Opinion on risks for animal and public health related to the presence of T-2 and HT-2 toxin in food and feed. EFSA Journal 2011;9(12):2481, 187 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011c. Scientific Opinion on pyrrolizidine alkaloids in food and feed. EFSA Journal 2011;9(11):2406, 134 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011d. Scientific Opinion on polybrominated diphenyl ethers (PBDEs) in food. EFSA Journal 2011;9(5):2156, 274 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011e. Scientific Opinion on hexabromocyclododecanes (HBCDDs) in food. EFSA Journal 2011;9(7):2296, 118 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2012. Scientific Opinion on ergot alkaloids in food and feed. EFSA Journal 2012;10(7):2798, 158 pp.

Ehlers S, 2012. Analytik von Perfluoralkylsäuren in verschiedenen Matrices zur Klärung der Toxikokinetik in Tierarten, die der Lebensmittelgewinnung dienen. PhD Thesis. 229 pp.

EMEA (The European Agency for the Evaluation of Medicinal Products), 1997a. Committee for Veterinary Medicinal Products. Furazolidone. Summary report. 3 pp. Available online http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500014332.pdf

EMEA (The European Agency for the Evaluation of Medicinal Products), 1997b. Committee for Veterinary Medicinal Products. Metronidazole. Summary report. 5 pp. Available online http://www.emea.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500015087.pdf

EMEA (The European Agency for the Evaluation of Medicinal Products), 2009. Committee for Veterinary Medicinal Products. Chloramphenicol. Summary report. Available online http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500012060.pdf

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization), 1988. Expert Committee on Food Additives. Chloramphenicol—toxicological evaluation of certain veterinary drug residues in food, WHO Food Additives Series 23, WHO, Geneva, 1–71. Available online http://www.inchem.org/documents/jecfa/jecmono/v23je02.htm

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives) 2004. Evaluaion of certain veterinary drug residues in food. Sixty-second meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), Rome, Italy, 4–12 February 2004. WHO Technical Report Series 925, WHO, Geneva. Available from http://whqlibdoc.who.int/trs/WHO_TRS_925.pdf

Focant JF, Eppe G, Pirard C, Massart AC, André JE and De Pauw E, 2002. Levels and congener distributions of PCDDs, PCDFs and non-ortho PCBs in Belgian foodstuffs— assessment of dietary intake. Chemosphere, 48, 167–179.

Hamscher G, Priess B, Nau H and Panariti E, 2005. Determination of colchicine residues in sheep serum and milk using high-performance liquid chromatography combined with electrospray ionization ion trap tandem mass spectrometry. Analytical Chemistry, 77, 2421–2425.

Hoenicke K, Gatermann R, Hartig L, Mandix M and Otte S, 2004. Formation of semicarbazide (SEM) in food by hypochlorite treatment: is SEM a specific marker for nitrofurazone abuse? Food Additives and Contaminants, 21, 526–537.

Hoogenboom LAP, Berghmans MCJ, Polman THG, Parker R and Shaw IC, 1992. Depletion of protein-bound furazolidone metabolites containing the 3-amino-2-oxazolidinone side-chain from liver, kidney and muscle tissues from pigs. Food Additives and Contaminants, 9, 623–630.

IARC (International Agency for Research on Cancer), 1979. Monographs on the evaluation of carcinogenic risks to humans. Sex hormones (II). Volume 21. Available from http://monographs.iarc.fr/ENG/Monographs/vol21/volume21.pdf

IARC (International Agency for Research on Cancer), 1990. IARC Monographs on the evaluation of carcinogenic risks to humans. Pharmaceutical drugs. Volume 50. Available from http://monographs.iarc.fr/ENG/Monographs/vol50/mono50.pdf

IARC (International Agency for Research on Cancer), 2001. IARC Monographs on the evaluation of carcinogenic risks to humans. Some thyrotropic agents. Volume 79. Available from http://monographs.iarc.fr/ENG/Monographs/vol79/mono79.pdf

IARC (International Agency For Research On Cancer), 2012. IARC Monographs on the evaluation of carcinogenic risks to humans. Pharmaceuticals. Volume 100 A. A review of human carcinogens. Available from http://monographs.iarc.fr/ENG/Monographs/vol100A/mono100A.pdf

Kearns CF, McKeever KH, Malinowski K, Struck MB and Abe T, 2001. Chronic administration of therapeutic levels of clenbuterol acts as a repartitioning agent. Journal of Applied Physiology, 91, 2064–2070.

Klaassen CD, Liu J and Choudhuri S, 1999. Metallothionein: an intracellular protein to protect against cadmium toxicity. Annual Review of Pharmacology and Toxicology, 39, 267–294.

Koizumi N, Inoue Y, Ninomiya R, Fujita D and Tsukamoto T, 1989. Relationship of cadmium accumulation to zinc or copper concentration in horse liver and kidney. Environmental Research, 49, 104–114.

Levang J, Muller P, Girardin P and Humbert P, 2008. Sweet's syndrome and phenylbutazone-induced sialadenitis. Annales de Dermatologie et de Vénéréologie, 135, 291–294.

Lewis BP and Wilken LO, 1982. Veterinary drug index. Eds Yang SLT and Lewis PG. W.B. Saunders Company, Philadelphia, PA, USA, 76–77.

Lizarraga I, Sumano H and Brumbaugh GW, 2004. Pharmacologic and pharmacokinetic differences between donkeys and horses. Equine Veterinary Education, 16, 102–112.

Loizzo A, Gatti GL, Macri A, Moretti G, Ortolani E and Palazzesi S, 1984. Italian babyfood containing diethylstilbestrol—3 years later. Lancet, 1, 1014–1015.

Mealey KL, Matthews NS, Peck KE, Ray AC and Taylor TS,1997. Comparative pharmacokinetics of phenylbutazone and its metabolite oxyphenbutazone in clinically normal horses and donkeys. American Journal of Veterinary Research, 58, 53–55.

Nordberg M, 2004. Environmental exposure and preventive measures in Sweden and EU. Biometals, 17, 589–592

Pearson EG, 1991. Liver failure attributable to pyrrolizidine alkaloid toxicosis and associated with inspiratory dyspnoea in ponies—3 cases (1982–1988). Journal of the American Veterinary Medical Association, 198, 1651–1654.

Sarnsonova JV, Douglas AJ, Cooper KM, Kennedy DG and Elliott CT, 2008. The identification of potential alternative biomarkers of nitrofurazone abuse in animal derived food products. Food and Chemical Toxicology, 46, 1548–1554.

Singh MK, Gupta AK and Yadav MP, 2005. The donkey: its role and the scope for better management. Livestock International, 9, 18–20.

Soma LR, Uboh CE and Maylin GM, 2012. The use of phenylbutazone in the horse. Journal of Veterinary Pharmacology and Therapeutics, 35, 1–12.

Starkey P and Starkey M, 2000. Regional and world trends in donkey populations. In: Donkeys, people and development. Eds Starkey P and Fielding D. ACP-EU Technical Centre for Agricultural and Rural Cooperation (CTA), Wageningen, the Netherlands, 10–21.

Tarantola M, Schiavone A, Preziuso G, Russo C, Biolatti B and Bergero D, 2004. Effects of low doses of dexamethasone on productive traits and meat quality of veal calves. Animal Science, 79, 93–98.

Wagner SA, Mostrum MS, Hammer CJ, Thorson JS and Smith DJ, 2008. Adverse effects of zilpaterol administration in horses: three cases. Journal of Equine Veterinary Sciences, 28, 238–243.

Waltner-Toews D and McEwen SA, 1994. Residues of hormonal substances in foods of animal origin: a risk assessment. Preventive Veterinary Medicine, 20, 235–247.

Watson DH, 2004. Pesticide, veterinary and other residues in food. Woodhead Publishing Ltd, Cambridge, UK, 686 pp.

Annex A. Analytical methods: performance characteristics and validation

1. Method performance

Commission Decision 2002/657/EC specifies the performance characteristics and interpretation of results for analytical methods used to implement the residue monitoring required by Council Directive 96/23/EC. According to this decision, suitable screening methods are those for which it can be demonstrated in a documented traceable manner that they are validated and have a false compliant rate of <5 % at the level of interest. In the case of confirmatory methods, distinction is made between those methods suitable for confirming the presence of prohibited (Group A) substances and those that may be used for confirming the presence of licensed veterinary drugs and contaminants (Group B substances). For Group A substances, LC (liquid chromatography) or GC (gas chromatography) separation with MS or IR spectrometric detection is required and, in the case of MS techniques where mass fragments are produced, the relationship between different classes of mass fragment and identification points are specified, with a minimum of 4 identification points being required for confirmation. Apart from LC or GC chromatographic separation with MS (mass spectrometry) or IR (infrared) spectrometric detection, suitable confirmatory techniques for Group B substances may include LC with diode-array or fluorescence detection for appropriate molecules, two-dimensional thin layer chromatography (2-D TLC) with full-scan UV/VIS detection, and gas chromatography with electron capture detector (GC-ECD), LC-immunogram or LC-UV/VIS where at least two different chromatographic separations are used.

Commission Decision 2002/657/EC specifies the performance criteria for methods, including recovery and accuracy, trueness and precision. The Decision specifies, also, the validation required to demonstrate that each analytical method is fit for purpose. In the case of screening methods, validation requires determination of the performance characteristics of detection limit (CCβ), precision, selectivity/specificity and applicability/ruggedness/stability. For confirmatory methods, in addition to determination of those performance characteristics, validation requires, also, determination of decision limit (CCα) and trueness/recovery.

The analytical requirements for the determination of dioxins, dioxin-like and non dioxin-like PCBs are laid down in Commission Regulation (EC) No 252/2012[47]. Following a criteria approach analyses can be performed with whatever method, provided the analytical performance criteria are fulfilled. While methods, such as GC-MS, cell-and kit-based bioassays are allowed for screening purposes, the application of GC/high resolution MS is mandatory for confirmation of positive results.

2. Screening methods

Screening methods include a broad range of methods, such as enzyme-linked immunosorbent assays, biosensor methods, receptor assays, bioassays and biomarkers for the presence of residues of concern. These screening methods generally use specific binding of the molecular structure of the residue(s) by antibodies or other receptors to isolate and measure the presence of the residues in biological fluids (urine, plasma) or sample extracts. More recently, biomarkers for the use of prohibited substances such as hormonal growth promoters have been identified as potential screening methods for these substances. Physico-chemical methods, such as LC or GC with various detectors, may be used, also, as screening methods.

In the particular case of antimicrobials, microbiological or inhibitory substance tests are widely used for screening. In such tests, using multiple plates/organisms or kit formats, the sample or sample extract is tested for inhibition of bacterial growth. If, after a specific period of incubation, the sample inhibits the growth of the bacteria, it is considered that an antibacterial substance is present in the sample, but the specific substance is not identified. Given that this is a qualitative analytical method, a

[47] Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006. OJ L 84, 23.3.2012, p. 1–22.

misinterpretation of the results cannot be ruled out, and some false positives can occur. Microbiological methods are screening methods which allow a high sample throughput but limited information is obtained about the substance identification and its concentration in the sample. When residues are found in a screening test, a confirmatory test may be carried out, which normally involves a more sophisticated testing method providing full or complementary information enabling the substance to be identified precisely and confirming that the MRL has been exceeded.

3. Confirmatory methods

With the significant developments in liquid chromatography and in mass spectrometry over the last decade, confirmatory methods are largely MS-based, using triple quadrupole, ion trap, and other MS techniques. Indeed, with current methodology in a modern residue laboratory with good MS capability, much of the two-step approach of screening followed by confirmatory testing has been replaced by single confirmatory testing. This has been made possible by the greatly-enhanced separation capability of ultra high performance liquid chromatography (UPLC), coupled with sophisticated MS detection systems. The parallel growth in more efficient sample extraction/clean-up methods is an integral part of these advances in confirmatory methods and such chemistries produce rapid, sometimes (semi)-automated procedures providing multi-residue capability. Techniques based on highly-efficient sorbent chemistries for solid-phase extraction and techniques such as QuEChERS (Quick Easy Cheap Effective Rugged Safe) are examples of these advances. Such combination of UPLC-MS/MS methods with appropriate sample extraction/cleanup technologies allows for unequivocal, quantitative determination of a broad spectrum of substances in a single analytical method.

Particularly in the area of prohibited substances, the power of MS techniques is being applied to identify hitherto unknown compounds and to identify exogenous from endogenous substances. For example, time-of-flight MS provides accurate mass capability and may allow for retrospective analysis capability from the MS data. The technique of GC–combustion–isotope ratio MS has been utilised to study the $^{13}C/^{12}C$ ratio of substances in urine samples, where, for example, such $^{13}C/^{12}C$ ratio differs significantly between endogenous (or natural) testosterone and exogenous (or synthetic) testosterone.

ABBREVIATIONS

ADI	acceptable daily intake
AFSSA	Agence Française de Sécurité Sanitaire des Aliments
AHD	1- amino-hydantoin
BIOHAZ Panel	EFSA Panel on Biological Hazards
BIOMO	EFSA Biological Monitoring Unit
BMDL	benchmark dose lower confidence limit; 95 %- confidence lower bound
$BMDL_{10}$s	benchmark dose lower confidence limits for a benchmark response of 10 %
b.w.	body weight
CCα	decision limit
CCß	detection limit
CONTAM Panel	EFSA Panel on Contaminants in the Food Chain
CVMP	Committee for Medicinal Products for Veterinary Use of the European Medicines Agency
CVO	Chief Veterinary Officer
DDT	dichlorodiphenyltrichloroethane
DL-PCB	dioxin-like polychlorinated biphenyl
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EU	European Union
FCI	food chain information
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed
FEI	Fédération Equestre Internationale
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
HBCDD	hexabromocyclododecanes
HCH	hexachlorocyclohexanes
IARC	International Agency for Research in Cancer
LC	liquid chromatography
ML	maximum level
MOE	margin of exposure
MRL	maximum residue limit
MRPL	minimum required performance limit
MS	mass spectrometry
MS	member state
MT	metallothionein

NC	non-compliant
NDL-PCBs	Non dioxin-like polychlorinated biphenyl
NRCP	national residue control plan
NSAID	non-steroidal anti-inflammatory drug
OIE	World Organisation for Animal Health
PBDE	polybrominated diphenylethers
PCB	polychlorinated biphenyls
PCDD	polychlorinated dibenzo-*p*-dioxin
PCDF	polychlorinated dibenzofurans
PFOA	perfluorooctanoic acid
PFC	perfluorinated compound
PFOS	perfluorooctane sulphonate
PSM	plant secondary metabolite
RAL	resorcylic acid lactone
RASFF	Rapid Alert System for Food and Feed
SAS	EFSA Scientific Assessment Support Unit
T3	triiodothyronine
T4	thyroxine
TDI	tolerable daily intake
TEQ	toxic equivalent
TOR	terms of reference
TSE	transmissible spongiform encephalopathy
TWI	tolerable weekly intake
UPLC	ultra-high-performance liquid chromatography
VMP	veterinary medicinal product
WHO	World Health Organization

Appendix C. Assessment on animal health and welfare

SUMMARY

This opinion focuses on the implications for animal health and welfare of changes to the current meat inspection system, as proposed by the Biological Hazards (BIOHAZ) and Contaminants in the Food Chain (CONTAM) Panels. ‘‘Implications for animal health and welfare” relates specifically to monitoring and surveillance of animal health and welfare during meat inspection (that is, inspection at the slaughterhouse before and after slaughter, in this document referred to as *ante-mortem* and *post-mortem* inspection, respectively). Therefore, the objective of this work was to identify possible effects and to assess the possible consequences for the surveillance and monitoring of animal diseases and welfare conditions if the proposed changes on meat inspection system were applied. The proposed changes analysed were (i) omission of palpation and incision in animals subjected to routine slaughter at *post-mortem* inspection, (ii) improvement of animal traceability, and (iii) improvement of the food chain information system. To assess the impact of changes to the current meat inspection system on the overall sensitivity for surveillance and control of animal diseases and welfare conditions, a quantitative assessment was performed based on expert opinion and modelling. An external consortium (COMISURV), under the provision of an EFSA procurement, performed this work. The detailed methodology, as well as results and conclusions, together with assumptions and limitations of the modelling, have been addressed in the COMISURV report. Diseases and welfare conditions considered were those having a high likelihood of detection at meat inspection where the surveillance component provided by meat inspection was significant for the whole surveillance of the condition. Furthermore, only conditions relevant to animal health and welfare and present in the EU, were considered. A total of eighteen conditions (fourteen diseases and four welfare conditions) were included in the assessment.

A stochastic model to quantify the monitoring and surveillance effectiveness of meat inspection in solipeds was developed. Definitions of typical and mild cases of each of the diseases and welfare conditions assessed were provided by experts, and the proportion of presentation of each of them was estimated. The most likely detection probability, as well as the 5th and 95th percentiles (the probability intervals), were derived for each of the conditions under both the current meat inspection system and a visual only system.

The probability of detection was calculated for both detectable cases (mild and typical), and for all cases (Stage 2) further modelling (Stage 3) was implemented to quantify the effectiveness of monitoring and surveillance (detection probability, component-specific and overall detection fraction) in the overall monitoring and surveillance system, both prior to and following suggested changes to the meat inspection system.

It should be noted that the word surveillance as used in this opinion does not imply that any action is taken to capture, or act upon, the information. It merely points to the potential of these systems to be used for such purposes.

A significant reduction (non-overlapping 90 % probability intervals) in the overall effectiveness of the meat inspection procedure in the visual only scenario was seen only for strangles, probably owing to the omission of palpation of the upper respiratory tract lymph nodes in the visual-only procedure. Nevertheless, the resulting probability of detection was still very high ($\geq$ 0.9).

The probability of detecting milder cases of rhodococcosis was also significantly reduced in the visual only scenario. In mild cases of rhodococcosis, small abscesses can be located deep in the lung parenchyma and palpation is an important way of detecting them.

A non-significant reduction of the detection probability was seen for glanders in the visual only scenario. This result was probably due to the fact that in the visual only scenario head splitting was not taken into consideration. Inspection tasks aimed at detecting lesions of glanders in the nasal cavity

(head splitting) may be performed if necessary, and this would not change with a move to a visual only system. Because of this, there should not be an impact on the surveillance of glanders

When the role of meat inspection was analysed in the overall surveillance (Stage 3), it was evident that meat inspection can play an important role in the detection of welfare conditions that are not detected during clinical surveillance; however, the proposed change in *post-mortem* inspection protocol, from conventional to visual only, did not affect the detection fraction for the two welfare conditions examined, lameness and poor body condition.

The consequences of a reduction in the detection fraction of strangles and rhodococcosis was analysed by experts. Strangles may be suspected during routine *ante-mortem* inspection by the presence of purulent nasal discharge and/or enlarged lymph nodes, and at *post-mortem* inspection by palpation of the lymph nodes of the head and neck (and mesenteric lymph nodes, if necessary, in the case of ‘‘bastard strangles’’), and the decrease in detection probability in a visual only system, although significant, is low. In the visual only scenario, routine palpation would be omitted, but if deemed necessary palpation and incision of lymph nodes could be done in suspect cases. The subclinical carrier stage, of great epidemiological relevance, may go undetected during routine *post-mortem* inspection as guttural pouch examination is not performed. Furthermore, several diagnostic tools are available to be used at farm level to aid in clinical surveillance. Taking this into account, the expert opinion is that the expected reduction in the detection level of strangles is unlikely to affect overall surveillance of this disease. In the case of rhodococcosis, mild cases of this disease may go undetected under the visual only scenario; however, the impact of this reduction was considered very low, and therefore the change to a visual only system is unlikely to affect the overall surveillance of this disease.

Improvements in food chain information and traceability were considered by the experts as not having a negative effect on animal health and welfare surveillance.

The assessment on animal health and welfare concluded that recommendations of the CONTAM Panel would not have a negative impact of surveillance of animal diseases and welfare conditions.

TABLE OF CONTENTS

ASSESSMENT

1. Introduction

In this mandate, the Animal Health and Welfare (AHAW) Panel and the *ad hoc* working group (WG) are focusing on the implications for animal health and welfare of any changes to the current meat inspection (MI) system, as proposed by BIOHAZ and CONTAM Panels. "Implications for animal health and welfare" relates specifically to monitoring and surveillance of animal health and welfare during MI (that is, inspection at the slaughterhouse before and after slaughter, in this document referred to as *ante-mortem* (AMI) and *post-mortem* inspection (PMI), respectively). Therefore, the objective of this work is to identify possible effects and to assess the possible consequences on surveillance and monitoring of animal diseases and welfare conditions if the proposed changes to the MI system were applied.

Apart from its contribution to assuring public health, current MI also contributes to the surveillance and monitoring of animal health and welfare (EFSA, 2003) and may be an important component of the overall monitoring and surveillance system, or even be the unique place allowing for monitoring some diseases and conditions at certain stages of a control and eradication programme. Therefore, any change in the MI system that could lead to a loss of sensitivity (reduced detection capability) may compromise the efficacy of surveillance.

AMI and PMI, collectively known as slaughterhouse surveillance system, play vital roles in the welfare monitoring of solipeds. The slaughterhouse surveillance system is the only place where poor welfare during transport of animals can be detected. Solipeds are subjected to different periods of feed and water restriction, handling and transport for long distances prior to arrival at a slaughterhouse. It is a statutory requirement in Europe to check that each animal is accompanied with an appropriate identification document (passport) by the food business operator (FBO) and verified by the official veterinarian (OV). AMI by the veterinarian then begins with the observation of animals at the time of unloading from the transport vehicle. The purpose is to determine whether animal welfare has been compromised in any way on the farm and during handling and transport. Welfare conditions such as fitness to travel, prevalence of broken limbs, lameness, exhaustion and poor body condition are ascertained during AMI. Certain other welfare condition such as bruising and injury may not always be detectable during AMI but become visible during routine PMI. Welfare conditions related to fracture and lameness would be detectable only if the animals are observed when walking, e.g. unloading or moving to lairage pens.

2. Implications for surveillance and monitoring for soliped health and welfare of changes to meat inspection as proposed by the BIOHAZ Panel

2.1. The proposed BIOHAZ Panel changes

The proposed modifications for the MI system which may have implications for animal health and welfare (see BIOHAZ Appendix A for full details) include:

- Omission of palpation and incision in animals subjected to routine slaughter at PMI. In case an abnormality is found that needs palpation, incision and head splitting, it is recommended that this is done away from the slaughter line (see BIOHAZ Appendix A, Section 5.2.3).
- Improvement of the traceability system (see BIOHAZ Appendix A, Section 3.5).
- Improvement of the Food Chain Information (FCI) system (see BIOHAZ Appendix A, Section 5.2.1).

2.2. Quantitative assessment of the impact of changes on meat inspection on the effectiveness of the detection of animal diseases and welfare conditions (COMISURV report)

To assess the impact of proposed changes to the current MI on the overall sensitivity for surveillance and control of animal diseases and welfare conditions, a quantitative assessment was performed based on expert opinion and modelling. An external consortium (COMISURV), under the provision of an EFSA procurement, performed this work.

2.2.1. Materials and methods

The detailed methodology, as well as results and conclusions, together with assumptions and limitations of the modelling, can be found in the COMISURV report for soliped MI (Laugier et al., 2012). These limitations include:

- The parameters for the probability of detection were based on expert opinion and therefore there is uncertainty as to the true range of these values
- Scarcity of peer reviewed scientific literature on the role of MI on surveillance of soliped diseases and welfare conditions.
- Limited number of experts to cover the different subjects needed for the assessment.
- Variations in the epidemiological situation of the disease and welfare conditions between countries.

A brief description of the methodology that was applied in the COMISURV report is given below.

2.2.1.1. Identification of diseases and conditions which could be affected by changes in MI

An initial long list of soliped diseases and welfare conditions relevant to the EU was established, based on general textbooks, references, and expert opinion. WG experts filtered this list using a decision tree, following previous methodology and criteria developed for previous opinions (EFSA BIOHAZ, CONTAM and AHAW Panels, 2011, 2012). A disease or welfare condition was retained on the list by the WG experts using the following criteria, when:

- A high likelihood of detection of a disease or welfare condition at MI, at the age that animals are presented at the slaughterhouse (if likelihood was medium, low or the condition was undetectable, it was excluded from the list).
- The disease or welfare condition is considered relevant to the EU (conditions not occurring in EU Member States were omitted).
- The conditions are relevant to animal health and welfare (conditions mainly relevant to public health were not retained, as they should be dealt with by the BIOHAZ Panel).
- The slaughterhouse surveillance component (AMI + PMI) provided by MI is significant for the overall surveillance of the disease or welfare condition (if there are other surveillance or detection systems much more effective and highly preferable to MI, the conditions were removed from the list).

The final list of conditions established by the WG experts to be assessed by the COMISURV consortium is shown in Table 1. A total of eighteen conditions (fourteen diseases and four welfare conditions) were included in this list.

2.2.1.2. Development of a stochastic model to quantify the effectiveness of MI

A stochastic model to quantify the monitoring and surveillance effectiveness of MI in solipeds was developed. A definition of a typical and a mild case of each of the diseases and welfare conditions listed in Table 1 was provided by the COMISURV experts.

Typical cases were by definition detectable cases and express more developed clinical signs than mild cases. Typical cases were defined as the clinical signs and/or lesions that are expected to be observed in more than 60 % of affected or infected solipeds arriving at slaughter.

The mild case of a disease or welfare condition is the form that could be seen at the early stages of the disease or at some point between the subclinical (and without pathological lesions that are observable through the MI process) and the fully developed form (i.e. 'typical' form). A mild case is neither typical nor non-detectable. The animal will probably present more subtle signs than the typical case. As an example, a typical case of *Rhodococcus equi* infection was one showing multiple large caseous abscesses in the cranioventral regions of the lungs, mucopurulent exudates in the airways and mediastinal and tracheobronchial lymphadenopathy with abscesses, whereas a mild case would show few small abscesses in the lung parenchyma.

The proportion of presentation of each of these forms, as well as the non-detectable fraction, was estimated (see COMISURV report for details).

The most likely detection probability, as well as 5^{th} and 95^{th} percentiles (the probability intervals) of the output distribution of AMI and PMI, and both combined, were derived for each of the conditions in Table 1 (both prior to and following suggested changes to the MI system as proposed by the BIOHAZ Panel. The inspection protocols in the current and visual only systems are compared in Table 2. Head splitting is not routinely performed during MI of solipeds; however, according to Regulation (EC) 854/2004, the head may be split if necessary in suspect cases of glanders.

The probability of detection was calculated for both detectable cases (mild and typical) and for all cases (referred to as Stage 2 in the COMISURV report).

Table 1: List of diseases and welfare conditions in solipeds identified by the AHAW WG (Stage 1) for consideration in the assessment conducted by COMISURV

Character of disease	List of diseases/ conditions	Stage 2[a]	Stage 3[b]
Exotic			
	Glanders	X	
	West Nile fever	X	
Endemic			
	Acute viral respiratory infection	X	X
	Bacterial pleuropneumonia	X	X
	Echinococcosis/hydatidosis	X	
	Equine sarcoid	X	
	Fasciolosis	X	
	Fungal diseases of the respiratory tract	X	
	Grass sickness	X	
	Intestinal clostridiosis	X	
	Myopathy	X	
	Rhodococcosis	X	
	Salmonellosis	X	
	Strangles	X	X
Welfare conditions			
	Poor body condition	X	X
	Broken limb	X	
	Lameness (except limb fracture)	X	X
	Injuries, bruises and skin lesions	X	

a: Stage 2—All diseases and welfare conditions listed were evaluated with regards to their probability of being detected at MI.
b: Stage 3—For selected diseases and welfare conditions, surveillance by MI was to be compared with clinical surveillance.

Table 2: List of AMI and PMI soliped inspection tasks according to Regulation (EC) 854/2004 (the current procedure) and changes in procedure resulting from the change to visual inspection (visual only). (V, visual inspection; I, incision; P, palpation). Shaded boxes indicate inspection points where the visual only scenario implies a change to the current procedure

Inspection step		Inspection procedure	
		Current	**Visual only**
***Ante-mortem* inspection**			
Food chain information	Diseases, morbidity and mortality on farm	V	V
Live animal	General health	V	V
***Post-mortem* inspection**			
Whole carcass	External surface	V	V
Head	Head and throat	V	V
	Retropharyngeal lymph node	P + I[b]	V
	Submaxillary and parotid lymph nodes	P + I[b]	V
	Mouth and fauces	V	V
	Tongue	V + P	V
Lungs	Parenchyma	V + P + I[a]	V
	Trachea	V + I[a]	V
	Major bronchi	I[a]	V
	Mediastinal lymph node	P + I[b]	V
	Bronchial lymph node	P + I[b]	V
Oesophagus		V	V
Heart	Heart	V + I	V
	Pericardium	V	V
Diaphragm		V	V
Liver	Parenchyma	V + P + I[b]	V
	Hepatic lymph node (= portal)	V + P + I[b]	V
	Pancreatic lymph node	V + P + I[b]	V
Gastro Intestinal tract	Stomach and intestines	V	V
	Mesentery	V	V
	Gastric lymph node	V + I[b]	V
	Mesenteric lymph node	V + I[b]	V
Spleen		V + P[c]	V
Kidneys	Parenchyma	V + P + I[b,f]	V
	Renal LN	I[b]	V
Uterus and mammary glands	Uterus	V	V
	Udder	V	V
	Supra-mammary lymph node	V + I[b]	V
Male genital tract	Testicles	V[e]	V
	Penis	V[e]	V
Pleura		V	V
Peritoneum		V	V
Umbilical area		V + P + I[d]	V
Joints		V + P + I[d]	V
Synovial fluid		V	V
Shoulders	Muscles	V[f]	V[f]
	Axillary lymph node	V[f]	V[f]

a: If organs are destined for human consumption.
b: Incision only if considered necessary.
c: Palpation only if considered necessary.
d: Incision in the event of doubt.
e: If available.
f: Mandatory in white and grey horses.

In addition, for three of the selected diseases and two welfare conditions considered to be more adversely affected in terms of detection probability following the proposed changes to the MI system further modelling was implemented to quantify the effectiveness of monitoring and surveillance (detection probability, component specific and overall detection fraction) in the overall monitoring and surveillance system, both prior to and following suggested changes to the MI system (referred to as Stage 3 in the COMISURV report).

Note that the word surveillance as used in this opinion does not imply that any action is taken to capture, or act upon, the information. It merely points to the potential of these systems to be used for such purposes.

2.2.2. Results and discussion

The probability of detection for each disease and welfare condition using the current MI system (Stage 2) and the visual only system is shown in Table 3, (detectable cases (mild or typical)) and Table 4 (detectable (case-type-specific) cases (typical and mild)). A significant reduction (non-overlapping 90 % probability intervals) in the overall effectiveness of the MI procedure in the visual only scenario was seen only for strangles (Tables 3 and 4). This reduction may be explained by the omission of palpation of the upper respiratory tract lymph nodes in the visual only procedure, which is useful to detect strangles. Nevertheless, the resulting probability of detection was still very high (≥ 0.9).

The probability of detecting milder cases in the visual only scenario was significantly reduced only for rhodococcosis (see Table 4). In mild cases of rhodococcosis, small abscesses can be located deep in the lung parenchyma and palpation is an important way of detecting them. Fasciolosis was the disease with the lowest detection effectiveness, in the current system as well as in the visual only scenario. PMI did not have any added value for the detection of West Nile fever. This result is not surprising, based on the fact that lesions of West Nile fever are limited to the brain and spinal cord and are usually only detectable by microscopic examination.

A non-significant reduction in detection probability was seen for glanders in the visual only scenario (Table 3 and 4). This result was probably owing to the fact that in the visual only scenario head splitting was not taken into consideration. Inspection tasks aimed at detecting lesions of glanders in the nasal cavity (head splitting) may be performed if necessary, and this would not change if moving to a visual only system. Owing to this, there should not be an impact on the surveillance of glanders.

Of the diseases and welfare conditions that were negatively influenced by the visual only scenario, only the parasitic diseases had a detection effectiveness ≤ 0.1 at AMI (see Table A in Annex A). When the proportion of non-detectable cases was also taken into account, there were no significant differences in the detection fraction between the two inspection scenarios (see Table A in Annex A). As expected, MI was considered to have a lesser value for the overall detection capacity for diseases with a high proportion of non-detectable cases such as West Nile fever, fasciolosis and fungal diseases of the respiratory tract. For such diseases, surveillance methods that do not depend on the detection of clinical signs (e.g. methods that detect the pathogen or exposure to the pathogen) have the potential to be more effective.

In contrast, fractions detected at MI were ≥ 0.75 or ≥ 0.9 for four diseases (grass sickness, intestinal clostridiosis, salmonellosis, strangles) and all welfare conditions. These diseases and conditions all have characteristics that may explain these results: an absence or a low proportion of subclinical cases and/or clinical signs or lesions easy to detect. These are diseases and conditions for which MI is a potentially important surveillance tool, in particular if other methods for detection are lacking.

The quantitative analysis indicated that the proposed change in PMI to visual only inspection will not affect the detection of welfare conditions in solipeds (Table 3), and the effectiveness of detection was found to be higher for the combination of AMI and PMI than for either of these components on its own.

Table 3: The probability of detection of eighteen soliped diseases and welfare conditions at AMI and PMI, given that cases are detectable (mild or typical) (i.e. detection effectiveness). Note that PMI estimates are conditional on cases not being detected at AMI. Detection probabilities were derived for two different PMI scenarios. Most likely values (ML) and 5th and 95th percentiles are given

	AMI			PMI						Combined AMI and PMI					
	Current			Current			Visual only			Current			Visual only		
Diseases and conditions	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**
Exotic															
Glanders	0.66	0.76	0.83	0.10	0.15	0.22	0.03	0.05	0.09	0.86	0.92	0.94	0.74	0.80	0.87
West Nile fever	0.34	0.44	0.54	0.00	0.00	0.01	0.00	0.00	0.01	0.34	0.43	0.55	0.34	0.43	0.54
Endemic															
Acute viral respiratory infection	0.51	0.56	0.70	0.02	0.05	0.12	0.02	0.04	0.07	0.58	0.66	0.74	0.56	0.66	0.73
Bacterial pleuropneumonia	0.78	0.84	0.91	0.06	0.11	0.16	0.06	0.11	0.16	0.93	0.95	0.98	0.92	0.96	0.98
Echinococcosis/hydatidosis	0.00	0.00	0.00	0.66	0.73	0.78	0.61	0.64	0.72	0.66	0.73	0.78	0.61	0.64	0.72
Equine sarcoid	0.29	0.40	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.29	0.40	0.50	0.29	0.40	0.50
Fasciolosis	0.00	0.00	0.00	0.17	0.33	0.44	0.14	0.23	0.39	0.17	0.33	0.44	0.14	0.23	0.39
Fungal diseases of the respiratory tract	0.46	0.62	0.71	0.11	0.16	0.25	0.05	0.08	0.16	0.67	0.79	0.85	0.57	0.71	0.80
Grass sickness	0.64	0.80	0.89	0.02	0.06	0.18	0.02	0.06	0.18	0.79	0.87	0.92	0.79	0.89	0.92
Intestinal clostridiosis	0.70	0.78	0.84	0.05	0.09	0.13	0.05	0.08	0.13	0.80	0.87	0.91	0.80	0.86	0.90
Myopathy	0.15	0.23	0.30	0.10	0.15	0.25	0.05	0.09	0.17	0.29	0.38	0.49	0.24	0.34	0.42
Rhodococcosis (*Rhodococcus equi*)	0.64	0.71	0.80	0.14	0.19	0.26	0.07	0.10	0.16	0.87	0.93	0.95	0.77	0.84	0.88
Salmonellosis	0.79	0.87	0.91	0.04	0.07	0.15	0.04	0.09	0.13	0.92	0.95	0.96	0.91	0.93	0.95
Strangles	0.72	0.76	0.83	0.13	0.18	0.22	0.10	0.14	0.17	0.93	0.95	0.96	0.88	0.91	0.93
Welfare															
Broken limb	0.79	0.90	0.97	0.03	0.09	0.20	0.03	0.06	0.19	0.98	1.00	1.00	0.97	1.00	1.00
Injuries, bruises and skin lesions	0.24	0.29	0.36	0.46	0.54	0.65	0.46	0.56	0.65	0.76	0.87	0.93	0.76	0.83	0.93
Lameness (except limb fracture)	0.22	0.39	0.58	0.21	0.31	0.54	0.21	0.32	0.54	0.59	0.80	0.89	0.59	0.79	0.89
Poor body condition	0.48	0.69	0.81	0.13	0.26	0.40	0.13	0.23	0.41	0.82	0.93	0.97	0.82	0.93	0.97

Shaded rows indicate diseases identified as having a significant reduction in the probability of detection in the visual only scenario.

Table 4: The overall probability of detection of 18 soliped diseases and conditions at meat inspection (AMI and PMI combined), for typical and mild cases. Detection probabilities were derived for two different inspection scenarios defined by a working group under the EFSA AHAW Panel. Most likely values (ML) and 5th and 95th percentiles are given

	Typical cases						Mild cases					
	Current			Visual only			Current			Visual only		
Diseases and conditions	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**
Exotic												
Glanders	0.94	0.98	0.99	0.82	0.90	0.97	0.75	0.83	0.90	0.59	0.70	0.80
West Nile fever	0.62	0.72	0.90	0.61	0.74	0.89	0.21	0.33	0.44	0.21	0.33	0.44
Endemic												
Acute viral respiratory infection	0.77	0.87	0.94	0.75	0.83	0.92	0.10	0.25	0.35	0.10	0.25	0.35
Bacterial pleuropneumonia	0.97	1.00	1.00	0.97	1.00	1.00	0.89	0.94	0.97	0.87	0.93	0.97
Echinococcosis/hydatidosis	0.86	0.93	0.94	0.86	0.93	0.94	0.64	0.70	0.76	0.58	0.63	0.69
Equine sarcoid	0.74	0.88	0.96	0.74	0.88	0.96	0.10	0.23	0.38	0.10	0.23	0.38
Fasciolosis	0.69	0.79	0.88	0.69	0.79	0.88	0.08	0.20	0.32	0.05	0.13	0.22
Fungal diseases of the respiratory tract	0.89	0.97	0.99	0.85	0.95	0.98	0.59	0.75	0.80	0.47	0.65	0.72
Grass sickness	0.86	0.96	0.99	0.86	0.96	0.99	0.03	0.11	0.31	0.03	0.11	0.31
Intestinal clostridiosis	1.00	1.00	1.00	0.99	1.00	1.00	0.59	0.71	0.80	0.59	0.71	0.80
Myopathy	0.70	0.85	0.90	0.68	0.80	0.88	0.20	0.35	0.43	0.15	0.26	0.34
Rhodococcosis (*Rhodococcus equi*)	1.00	1.00	1.00	0.99	1.00	1.00	0.80	0.87	0.91	0.63	0.73	0.80
Salmonellosis	0.98	1.00	1.00	0.96	0.98	0.99	0.58	0.68	0.76	0.57	0.65	0.75
Strangles	0.97	0.98	0.99	0.92	0.94	0.97	0.85	0.89	0.91	0.77	0.82	0.87
Welfare												
Broken limb	0.98	1.00	1.00	0.97	1.00	1.00	–	–	–	–	–	–
Injuries, bruises and skin lesions	0.91	0.97	0.99	0.91	0.97	0.99	0.66	0.81	0.92	0.66	0.80	0.92
Lameness (except limb fracture)	0.95	0.98	1.00	0.95	0.99	1.00	0.53	0.75	0.87	0.53	0.74	0.87
Poor body condition	0.82	0.93	0.97	0.82	0.93	0.97	–	–	–	–	–	–

Shaded rows indicate diseases identified as having a significant reduction in detection probability in the visual only scenario.

For three diseases and two welfare conditions, the relative effectiveness of slaughterhouse surveillance by MI within the overall surveillance system was assessed (Stage 3 in the COMISURV report). It should be noted that the word surveillance as used in the COMISURV report does not imply that any action is taken to capture, or act upon, the information. It merely points to the potential of these systems to be used for such purposes.

The results showed that the role of MI is very limited compared with clinical surveillance (defined as surveillance based on clinical observations in the field). This is mainly explained by the proportionally limited contribution of MI to surveillance of health and welfare in solipeds (low proportion of slaughtered solipeds over the whole population). However, for conditions that may be more difficult to detect clinically in stables, as perhaps some welfare conditions, MI may still play a significant role as an alarm system.

The results of quantitative analysis also indicated that the proposed change in PMI protocol, from conventional to visual only, did not affect the detection fraction for lameness and poor body condition (Tables 5 and 6). Clinical surveillance alone (Table 5) yielded a very low detection fraction for poor body condition (0.10) and a mediocre value for lameness (0.51), and these values did not change when combined with the current or visual only protocol (Table 6).

It was concluded in the COMISURV report that, for issues that may be more prevalent in stables that are less likely to be seen by a veterinarian, such as some welfare conditions, clinical surveillance is less effective, so MI may have a relatively more important role as an alarm system.

Table 5: Component-specific case-finding capacity of slaughterhouse and clinical surveillance, measured by detection fraction (presented as mode and 5th and 95th percentiles), for five endemic conditions in solipeds

	MI						Clinical surveillance		
	Current			Visual only					
Disease or condition	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**
Acute viral respiratory infection	0.0020	0.0024	0.0030	0.0020	0.0023	0.0030	0.27	0.32	0.37
Bacterial pneumonia	0.0075	0.0086	0.0105	0.0074	0.0084	0.0104	0.15	0.16	0.19
Strangles	0.0058	0.0067	0.0073	0.0056	0.0064	0.0070	0.45	0.48	0.50
Lameness	0.0060	0.0069	0.0076	0.0060	0.0068	0.0076	0.47	0.51	0.54
Poor body condition	0.0050	0.0052	0.0054	0.0049	0.0052	0.0054	0.08	0.10	0.12

Table 6: Overall case-finding capacity for slaughterhouse and clinical surveillance combined, measured by detection fraction (presented as mode and 5th and 95th percentiles), for five endemic conditions in solipeds. Two different MI scenarios were evaluated.

	Clinical surveillance + current MI			Clinical surveillance + visual only		
Disease or condition	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**
Acute viral respiratory infection	0.27	0.30	0.37	0.27	0.30	0.37
Bacterial pleuropneumonia	0.15	0.17	0.20	0.15	0.17	0.20
Strangles	0.46	0.47	0.51	0.46	0.48	0.51
Lameness	0.48	0.51	0.54	0.48	0.52	0.55
Poor body condition	0.08	0.10	0.13	0.08	0.10	0.13

2.3. Qualitative assessment of the role of meat inspection in surveillance programmes on selected diseases and welfare conditions

The qualitative assessment involved literature review and expert opinions from the WG members, for the selected diseases identified as having a significant reduction in detection probability of detectable cases in the quantitative assessment of the COMISURV report (strangles and rhodococcosis) and welfare conditions.

2.3.1. Strangles

2.3.1.1. Description of the disease and prevalence and relevance in EU

Strangles is a contagious bacterial disease of solipeds, caused by *Streptococcus equi* subsp. *equi* and remains one of the most commonly diagnosed infectious diseases of horses worldwide. The disease is initially characterised by a raised temperature and associated depression and loss of appetite. This is then followed several days later by profuse nasal discharge and swelling of the lymph nodes of the head and neck (submandibular and retropharyngeal lymph node) which burst, discharging highly infectious pus. The swelling of the lymph nodes in the head and neck may, in severe cases, restrict the airway and it is from this feature that the term 'strangles' arose.

Although most affected horses recover uneventfully over a period of about a week, some animals can become extremely ill for several days and fatal complications are not unusual. The more severe cases will take three to four weeks to make a full clinical recovery. Although clinical manifestations of *S. equi* infection are usually restricted to the head and neck, in a small proportion of cases other parts of the body may be affected, in the form of abscesses and related clinical problems. This condition is called "bastard strangles" and is frequently fatal. Another less common complication, which causes bleeding into the gums and other organs such as the lungs and may also be fatal, is referred to as "purpura haemorraghica" (syn. morbus maculosus).

A significant proportion of animals that recover from the disease remain to be carriers and continue to shed *S. equi* intermittently for prolonged periods (months and even years in some cases) after clinical signs have disappeared; the infection usually persists in the guttural pouches (Sweeney et al., 2007; Knowles, 2011). However, guttural pouches are not opened and examined during routine PMI. *S. equi* is highly host adapted, and few cases of infection in humans have been confirmed (Sweeney et al., 2007).

2.3.1.2. Surveillance system currently in place

Under the existing surveillance system diagnosis is based on the characteristic clinical signs and subsequently confirmed, if considered necessary based on culture (and/or polymerase chain reaction (PCR)) of nasopharyngeal swabs or pus, and/or serological testing by enzyme-linked immunosorbent assays (ELISA) (Sweeney et al., 2005; Knowles, 2011).

In 2008 the strangles ELISA blood test was launched by the Animal Health Trust. The test detects immunoglobulin G, to two *S. equi* specific antigens (A and C), identified through sequence analysis of *S. equi* and numerous strains of *S. zooepidemicus*. Exposure to *S. equi* within the last six months can be detected with a sensitivity of 93.3 %, and a specificity of 88.0 %. The test has proved popular and 5129 samples were submitted in 2010 (Knowles, 2011).

Slaughterhouse surveillance (PMI) only plays a minor role in monitoring this disease.

2.3.1.3. Impact of proposed changes on surveillance and control

During routine AMI strangles may be suspected if there is purulent nasal discharge and/or enlarged lymph nodes. In PMI strangles may be recognised by palpation of lymph nodes of the head and neck (and mesenteric lymph nodes, if necessary, in the case of "bastard strangles"). The subclinical carrier stage may go undetected during routine PMI as guttural pouch examination is not performed.

In the visual only scenario, routine palpation would be omitted, but if deemed necessary palpation and incision of lymph nodes could be done in suspect cases. Taking this into account, the expert opinion is that the expected reduction in the detection level of strangles is unlikely to affect overall surveillance of this disease.

2.3.2. Rhodococcosis

2.3.2.1. Description of the disease and prevalence and relevance in EU

Rhodococcosis (caused by *Rhodococcus equi)* is recognised worldwide as a major cause of disease in foals three weeks to six months of age. The most common clinical manifestation is pyogranulomatous pneumonia, although a variety of other clinical problems may be identified. Clinical disease is most commonly developed before four months of age. Infrequently, *R. equi* causes infection in adult horses, generally thought to be associated with immunosuppression. *R. equi* can be enzootic on farms and has been isolated from a wide variety of species, including cats, dogs, goats, cattle, camelids, pigs and other animals.

In some cases, *R. equi* infections can occur in other parts of the body, causing extra-pulmonary diseases. Those include joint infections, osteomyelitis, diarrhoea, inflammation of the lymph nodes in the abdomen, abdominal and spinal cord abscesses, hepatitis, and immune-mediated diseases (e.g., polysynovitis, uveitis, and anaemia). Foals with extra-pulmonary disease can have a different spectrum of clinical signs depending on the affected organ(s) (Oke, 2013).

Owing to its high fatality rate and the lack of effective early diagnosis and preventative measures, *R. equi* is recognised as one of the most important infectious problems that afflict equines worldwide (Vazquez-Boland, 2010).

2.3.2.2. Surveillance system currently in place

Rhodococcosis may be suspected at slaughterhouse by the presence of multiple firm nodules of different sizes in the lung, with some foci coalescing to form large lesions and partly atelectactic tissue. Occasionally, multiple miliary pyogranulomatous foci are present. The most common sites involved in *R. equi* infection other than the lung are the intestinal tract and mesenteric lymph nodes (Hines, 2007).

Clinical signs can be unspecific and subtle and early diagnosis may be difficult. In chronic cases the animals may show signs of fever, lethargy and decreased appetite. There is no routine officially recognised clinical surveillance system for this disease at present.

However, a number of PCR techniques have been developed to amplify either chromosomal or plasmid DNA of *R. equi* in a variety of samples. Using primers for virulence-associated protein A (VapA), virulent strains of *R. equi* can be rapidly identified. Although PCR can be a valuable diagnostic test, it should be used in conjunction with standard microbial culture because multiple bacterial pathogens may be present (Hines, 2007).

Serological assays have also been developed to detect *R. equi*-specific antibodies and they include ELISAs, an agar-gel immunodiffusion test and synergistic haemolysis inhibition assays (Hines, 2007).

2.3.2.3. Impact of proposed changes on surveillance and control

In a visual only scenario superficial lung lesions of rhodococcosis would still be detected; however, deeper lesions located in lung parenchyma would require palpation and incision. Mild cases of this disease may go undetected under the visual only scenario. Nevertheless, the expert opinion is that the expected reduction in the detection level of strangles is unlikely to affect overall surveillance of this disease.

2.3.3. Welfare conditions

Solipeds, especially horses, are often transported for long distances and durations and the detection of animal welfare conditions (broken limb, injuries, bruises and skin lesions, lameness and poor body condition) very much depend upon the slaughterhouse surveillance systems. A study involving 1008 horses arriving at two slaughterhouses in the USA found that around 8 % of horses had serious welfare problems (Grandin et al., 1999), which included emaciation (poor body condition), severe injury, lameness (non-ambulatory, moribund) or death. The injuries were mainly sustained during transport and subsequent to travel before slaughter.

The main factor that contributes to injury during transport is stocking density; however, loading orientation and design of transport vehicles may also contribute to the incidence of injuries and bruises. Collins et al. (2000) found that at higher stocking densities proportionally, more horses were injured during transport and there was a tendency for a higher number of injuries per horse. The number of falls, the time spent down and the injuries sustained as a result of a fall were also greater in the higher density group.

Most severe injuries that occur during transportation were also attributed to aggression from dominant horses (Grandin et al., 1999) and the inability of other horses to move away from bites and kicks, which seemed to play a significant role as stocking density increases (Collins et al., 2000). Cregier (1982) suggested that horses will preferentially protect their head and neck from injury, and tend to lift the head when forced to travel facing forwards, shifting weight onto the hind-quarters, resulting in decreased stability. Severe injuries occurring in slaughterhouses were mainly attributed to the penning together of unfamiliar horses (Grandin et al., 1999).

There is no peer-reviewed scientific publication regarding the prevalence of animal welfare conditions in solipeds at slaughter. Nevertheless, lameness has been stated to be a common welfare problem (see, CONTAM Appendix B of this opinion). However, the proposed change to visual only MI would not affect the detection of welfare conditions as revealed by the quantitative analysis.

2.4. Food chain information and traceability

The EU Regulation (EC) No 852/2004 on the hygiene of foodstuffs requires slaughterhouse operators to request FCI declarations to ensure animals entering the food chain are safe for human consumption. FCI is also a good source of information to facilitate the detection in the slaughterhouse of abnormalities indicative of animal diseases and welfare conditions. FCI is recorded at the group level, and its minimum content is described in Regulation (EC) No 853/2004. FCI related to primary production of solipeds is based on an owner or responsible person's declaration. Most MSs have standardised FCI declaration forms. A whole-chain approach to food safety, animal health and animal welfare requires FBOs to be provided by livestock producers with information about their animals consigned to slaughter. Based on the FCI provided, slaughterhouse operators can assess potential hazards presented by the animals and are required to act upon any information recorded on the FCI declaration as part of their hazard analysis and critical control point (HACCP) plan. This helps the slaughterhouse operator to organise slaughter operations and to ensure that no animals affected by disease or certain veterinary medicines enter the food chain. Quality assurance schemes at primary producer level are voluntary tools operated by independent agencies or bodies to ensure compliance with given standards and regulations. These schemes increase the owner or responsible person's responsibilities with regard to animal health and welfare and have the potential for integration within the FCI provided (OIE, 2006).

The FCI also assists risk management to determine the required inspection procedures and should be analysed by risk management and used as an integral part of the inspection procedures.

The value of the FCI in guiding risk management to discriminate between animals subsequently going through different types of inspection procedures should be evaluated. As for any evaluation of (pre-) screening procedures, the sensitivity and specificity of the classification should be estimated. Priority

should be given to improving test sensitivity, noting that (pre-) screening tests should preferably produce few false negative classifications for the sake of animal disease detection and surveillance. Test specificity will largely be an economical parameter, since the subsequent inspection of all "FCI-positive" animals or groups should detect any false positives not correctly identified during the FCI pre-screening.

Regulation (EC) No 853/2004 requires that data from the AMI and PMI at the slaughterhouse is delivered back to the owner or responsible person when the inspections reveal the presence of any disease or condition that might affect public or animal health or compromise animal welfare. Currently this feedback of information to primary producers is not fully implemented in all MSs (EFSA BIOHAZ, CONTAM and AHAW Panels, 2011). The UK Food Standards Agency (FSA) has carried out a study on the implementation of FCI since 2006 to explore ways of improving it (FSA, 2013). This study concludes that the effective and efficient flow of information provides valuable information to both the owner or responsible person and the FBO, allowing more targeted and effective inspection procedures in the slaughterhouse and effective interventions on the farm that should contribute to a cycle of continuous improvement with positive implications for animal health and welfare. The effectiveness of this information cycle depends on a reliable animal identification and recording system at the slaughterhouse and an information transfer system to the primary producer. The collection and communication of slaughterhouse inspection results is an opportunity to collect and use data and knowledge applicable to disease control and the effectiveness of interventions, animal production systems, food safety and animal health/welfare (Garcia, 2012). At national and EU level such data can contribute to disease surveillance (for the detection of exotic diseases, monitoring of endemic diseases and identification of emerging diseases) and targeted animal health and welfare interventions. Therefore FCI, if consistently and effectively implemented as enshrined within the hygiene package, will form an integral part of a risk-based MI system.

Extended use of FCI has the potential to compensate for some, but not all, of the information on animal health and welfare that would be lost if visual only PMI is applied. For the FCI to be effective it should include species-specific indicators for the occurrence of disease and welfare conditions. FCI for public health purposes may not have an optimal design for the surveillance and monitoring of disease and welfare conditions; therefore, an integrated system should be developed whereby FCI for public health and for animal health and welfare can be used in parallel, more effectively.

An effective and reliable individual animal identification system is vital to ensuring the traceability of animals as well as carcasses and meat derived from them. The lack of traceability in live soliped trade is not conducive to achieving effective traceability. Solipeds in Europe and those in countries exporting their meat to Europe (e.g. Canada, Mexico and South America) are not tagged as individual cattle or sheep are. However, it is worth noting that (as an example) although horses kept in the UK must have identification documents (commonly known as passports) with details of the owner and animal including drugs given to the animals for veterinary purposes, experience shows that the possibility of a horse being issued with two passports cannot be ruled out.

The FCI is an integral part of the traceability of animals from production to slaughter. For effective surveillance of diseases and welfare conditions one should be able to trace back animal movements until slaughter. Effective traceability would also help to assess risks for certain diseases and allow for a risk-based MI. For example the risk of glanders may be higher in endemic areas and PMI may require head splitting. Improvements in traceability, as recommended by the BIOHAZ Panel, are expected to have a positive impact on the surveillance of diseases and welfare conditions in solipeds.

3. Implications for surveillance and monitoring for soliped health and welfare of changes to meat inspection as proposed by the CONTAM Panel

The conclusions and recommendations from the CONTAM Panel refer to areas such as the ranking of chemical substances of potential concern and its updating, the use of FCI to help facilitate risk-based sampling strategies, the inclusion of new hazards in control programmes for chemical residues and

contaminants (see CONTAM Appendix B, for full details). None of these were considered to have an impact on animal health and welfare surveillance and monitoring.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- As shown by COMISURV, with a change from the current to a visual only inspection system, a significant reduction (non-overlapping 90 % probability intervals) in the overall effectiveness of the meat inspection procedure was seen only for strangles. Nevertheless, the resulting probability of detection was still very high (≥ 0.9).

- The change to a visual only system would have no impact on the detection probabilities of the four relevant animal welfare conditions included in the quantitative analysis by COMISURV.

- When the overall surveillance was assessed by COMISURV, the proposed change in *post-mortem* inspection protocol, from conventional to visual only, did not affect the detection fraction for the two welfare conditions examined, lameness and poor body condition.

- As shown by COMISURV, meat inspection can play an important role in the detection of some welfare conditions that are not detected during clinical surveillance.

- *Post-mortem* inspection plays a minor role in the diagnosis and surveillance of strangles and therefore a change to a visual only system is unlikely to affect overall surveillance of this disease.

- *Post-mortem* inspection plays a minor role in the diagnosis and surveillance of rhodococcosis and therefore a change to a visual only system is unlikely to affect overall surveillance of this disease.

- The prevalence of animal welfare conditions in solipeds arriving in slaughterhouses in Europe is not well documented.

- The proposed change to visual only meat inspection is not expected to affect the detection of animal welfare conditions.

- Extended use of food chain information has the potential to compensate for some, but not all, of the information on animal health and welfare that would be lost if visual only *post-mortem* inspection is applied.

- Improvements in traceability, as recommended from the assessment on biological hazards, are expected to have a positive impact on surveillance of diseases and welfare conditions in solipeds.

- Food chain information is a potentially effective tool to perform more targeted *ante-mortem* and *post-mortem* inspection tasks in the slaughterhouse that may increase the effectiveness of those tasks in detecting conditions of significance for animal health and animal welfare.

- The existing ineffective flow of information from primary production to the slaughterhouses and vice versa reduces the ability to detect animal diseases and animal welfare conditions at the slaughterhouse, and as a result it limits possible improvements on animal health and welfare standards as owners and responsible persons will not be aware of the slaughterhouse findings.

- None of the conclusions and recommendations on chemical hazards were considered to have an impact on animal health and welfare surveillance and monitoring.

RECOMMENDATIONS

- Studies are needed to ascertain the prevalence of animal welfare conditions in solipeds arriving in slaughterhouses in Europe.
- An integrated system should be developed whereby food chain information for public health and for animal health and welfare can be used in parallel, more effectively.
- For effective surveillance of diseases and welfare conditions one should be able to trace back animal movements up to slaughter.
- Owners or responsible persons should be provided with background information on the conditions of key concern that may affect their animals and why it is important to provide this information to the slaughterhouse through the use of food chain information.

REFERENCES

Collins MN, Friend TH, Jousan FD and Chen SC, 2000. Effects of density on displacement, fall, injuries and orientation during horse transportation. Applied Animal Behavioural Science, 67, 169–179.

COMISURV Report—Laugier C and Lindberg A, 2012. Contribution of meat inspection to animal health surveillance in solipeds. Supporting Publications EN-324, 57 pp. Available from http://www.efsa.europa.eu/en/efsajournal/doc/324e.pdf

Creiger SE, 1982. Reducing equine hauling stress: a review. Equine Veterinary Science, 2, 186–189.

EFSA (European Food Safety Authority), 2003. Scientific Opinion of the Panel on Biological Hazards (BIOHAZ) on a request from the Commission on tuberculosis and control in bovine animals: risks for human health strategies. The EFSA Journal, 13, 1–52.

EFSA Panels on Biological Hazards (BIOHAZ), on Contaminants in the Food Chain (CONTAM), and on Animal Health and Welfare (AHAW), 2011. Scientific Opinion on the public health hazards to be covered by inspection of meat (swine). EFSA Journal 2011;9(10):2351, 198 pp.

EFSA Panels on Biological Hazards (BIOHAZ), on Contaminants in the Food Chain (CONTAM), and on Animal Health and Welfare (AHAW), 2012. Scientific Opinion on the public health hazards to be covered by inspection of meat (poultry). EFSA Journal 2012;10(6):2741, 179 pp.

FSA (Food Standards Agency), 2013. An evaluation of food chain information (FCI) and collection and communication of inspection results (CCIR) for all species. FSA, London, UK, 144 pp.

Garcia AB, 2012. The use of data mining techniques to discover knowledge from animal and food data: examples related to the cattle industry. Trends in Food Science and Technology, 29, 151–157.

Grandin T, McGee K and Lanier JL, 1999. Prevalence of severe welfare problems in horses that arrive at slaughter plants. Journal of American Veterinary Medical Association, 214, 1531–1533.

Hines MT, 2007. Rhodococcus equi. In: equine infectious diseases. Eds Sellon DC and Long MT. Saunders Elsevier, St Louis, MO, USA, 281–295.

Knowles EJ, 2011. AHT/BEVA/DEFRA (Animal Health Trust/British Equine Veterinary Association/Department for Environment Food and Rural Affairs) equine quarterly disease surveillance report. Volume 7, No 2, April–June, 2011. Focus article: serological ELISA test for Streptococcus equi (Strangles), 11–12.

OIE (World Organisation for Animal Health), 2006. Animal production food safety working group. Guide to good farming practices for animal production food safety. Revue Scientifique et Technique, 25, 823–836.

Oke S, 2013, online. What you need to know about Rhodococcus equi. FACTSheet. Available from: http://www.thehorse.com

Sweeney CR, Timoney JF, Newton, JR and Hines MT, 2005. Streptococcus equi infections in horses: guidelines for treatment, control and prevention of strangles. Journal of Veterinary Internal Medicine, 19, 123–134.

Sweeney CR, Timoney JF, Newton JR and Hines MT, 2007. Streptococcus equi subsp. equi In: Equine infectious diseases. Eds Sellon DC and Long MT. Saunders Elsevier, St Louis, MO, USA, 245–256.

Vazquez-Boland JA, 2010. AHT/BEVA/DEFRA (Animal Health Trust/British Equine Veterinary Association/Department for Environment Food and Rural Affairs) equine quarterly disease surveillance report. Volume 6, No 4, September–December 2010. Focus article: recent advances in Rhodococcus equi, 13–17.

Annex A. Results from Stage 2 models

Table A: Fraction of all cases (mild, typical and non-detectable (subclinical) that are detected given they have entered the slaughterhouse, for eighteen soliped diseases and welfare conditions at AMI. Note that PMI estimates are conditional on cases not being detected at AMI. Detection probabilities were derived for two different PMI scenarios. Most likely values (mode) as well as 5th and 95th percentiles are given

	AMI			PMI						Combined AMI and PMI					
	Current			Current			Visual only			Current			Visual only		
Diseases and conditions	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**	**0.05**	**Mode**	**0.95**
Exotic															
Glanders	0.45	0.58	0.66	0.07	0.10	0.17	0.03	0.04	0.07	0.56	0.66	0.78	0.49	0.58	0.71
West Nile fever	0.07	0.10	0.12	0.00	0.00	0.00	0.00	0.00	0.00	0.07	0.09	0.12	0.07	0.10	0.12
Endemic															
Acute viral respiratory infection	0.36	0.45	0.53	0.02	0.03	0.08	0.01	0.03	0.05	0.41	0.48	0.56	0.39	0.47	0.55
Bacterial pleuropneumonia	0.51	0.60	0.67	0.04	0.07	0.11	0.04	0.07	0.11	0.59	0.67	0.74	0.59	0.69	0.74
Echinococcosis/hydatidosis	0.00	0.00	0.00	0.63	0.71	0.77	0.58	0.65	0.71	0.63	0.71	0.77	0.58	0.65	0.71
Equine sarcoid	0.28	0.39	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.28	0.39	0.50	0.28	0.39	0.50
Fasciolosis	0.00	0.00	0.00	0.01	0.02	0.03	0.01	0.01	0.02	0.01	0.02	0.03	0.01	0.01	0.02
Fungal diseases of the respiratory tract	0.07	0.15	0.20	0.02	0.03	0.07	0.01	0.02	0.04	0.10	0.16	0.26	0.09	0.16	0.24
Grass sickness	0.63	0.79	0.88	0.02	0.06	0.18	0.02	0.08	0.18	0.78	0.87	0.91	0.78	0.86	0.91
Intestinal clostridiosis	0.67	0.75	0.83	0.04	0.08	0.13	0.04	0.09	0.12	0.76	0.85	0.90	0.76	0.85	0.90
Myopathy	0.14	0.22	0.30	0.09	0.15	0.25	0.05	0.11	0.17	0.29	0.37	0.48	0.24	0.31	0.41
Rhodococcosis (*Rhodococcus equi*)	0.41	0.51	0.62	0.09	0.14	0.19	0.05	0.07	0.12	0.54	0.65	0.77	0.48	0.58	0.70
Salmonellosis	0.73	0.82	0.88	0.04	0.09	0.14	0.03	0.07	0.12	0.83	0.88	0.95	0.82	0.89	0.94
Strangles	0.61	0.67	0.73	0.11	0.16	0.19	0.08	0.12	0.15	0.78	0.82	0.86	0.74	0.78	0.83
Welfare															
Broken limb	0.79	0.90	0.97	0.03	0.09	0.20	0.03	0.06	0.19	0.98	1.00	1.00	0.97	1.00	1.00
Injuries, bruises and skin lesions	0.22	0.29	0.36	0.43	0.51	0.64	0.44	0.52	0.64	0.70	0.81	0.92	0.71	0.82	0.92
Lameness (except limb fracture)	0.21	0.32	0.57	0.21	0.32	0.53	0.21	0.33	0.53	0.58	0.80	0.88	0.58	0.78	0.88
Poor body condition	0.48	0.69	0.81	0.13	0.26	0.40	0.13	0.23	0.41	0.82	0.93	0.97	0.82	0.93	0.97

GLOSSARY AND ABBREVIATIONS

AHAW	Animal Health and Welfare (Panel)
AMI	*Ante-mortem* inspection
BIOHAZ	Biological Hazards (Panel)
CONTAM	Contaminants in the Food Chain (Panel)
EFSA	European Food Safety Authority
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
FBO	Food business operator
FCI	Food chain information
FSA	Food Standards Agency
HACCP	Hazard analysis and critical control point
I	Incision
MI	Meat inspection
MS	Member State
OIE	World Organisation for Animal Health
OV	Official veterinarian
P	Palpation
PCR	Polymerase chain reaction
PMI	*Post-mortem* inspection
V	Visual inspection
WG	Working group

All cases: the combination of detectable cases (mild and typical) and non-detectable cases.

Case-finding capacity: characteristic of a surveillance system for endemic disease, describing the ability of the system to identify infected or affected herds or individuals, so that a control action can (potentially) be taken. The detection fraction is a measure of the case-finding capacity.

Case type: includes detectable (mild or typical cases) and non-detectable cases.

Clinical surveillance: surveillance based on clinical observations in the field.

Detectable cases: cases that are detectable by routine meat inspection procedures. They will express a range of combinations of clinical and pathological signs. A proportion of detectable cases will fit the definition of the typical case and a proportion will be milder cases.

Detection effectiveness: the proportion of animals with lesions (i.e. detectable by visual inspection, palpation and/or incision) that are actually detected.

Detection fraction: the proportion of infected or affected units that are successfully detected by the surveillance system.

Mild cases: the mild case of a disease or condition is the form that could be seen at the early stages of the disease or at some point between the subclinical and the fully developed (i.e. "typical") form. A mild case is neither typical nor subclinical. The animal will probably present more subtle signs than in a typical case. Mild cases fit the mild case definition validated by experts.

Monitoring: investigating samples or animals in order to obtain information about the frequency of disease or infection as it varies in time and/or space.

Non-detectable cases: cases that are beyond the detection capacity of current meat inspection protocols. These will often be early cases at a stage where distinct clinical signs have not yet developed, but they can be cases with mild infection that leads to only subclinical conditions, without pathological lesions detectable by meat inspection.

Non-overlapping probability intervals: indicates that scenarios differ significantly from each other.

Overall surveillance system: includes several components, such as slaughterhouse surveillance and clinical surveillance.

Slaughterhouse surveillance: surveillance by meat inspection in slaughterhouses.

Stage 2: assessment of the probability of detection at meat inspection. The objective of Stage 2 modelling was to estimate case type-specific (for typical and mild cases) as well as overall probabilities of detection at meat inspection.

Stage 3: assessment of the relative effectiveness of meat inspection within the overall surveillance system by comparing meat inspection with other available surveillance methods.

Typical cases: cases that are, by definition, detectable cases and express more developed clinical signs than mild cases. They fit the typical case definition provided by the experts, which is defined as signs and/or lesions that are expected to be observed in more than 60 % of affected or infected of animals seen at the slaughterhouse.